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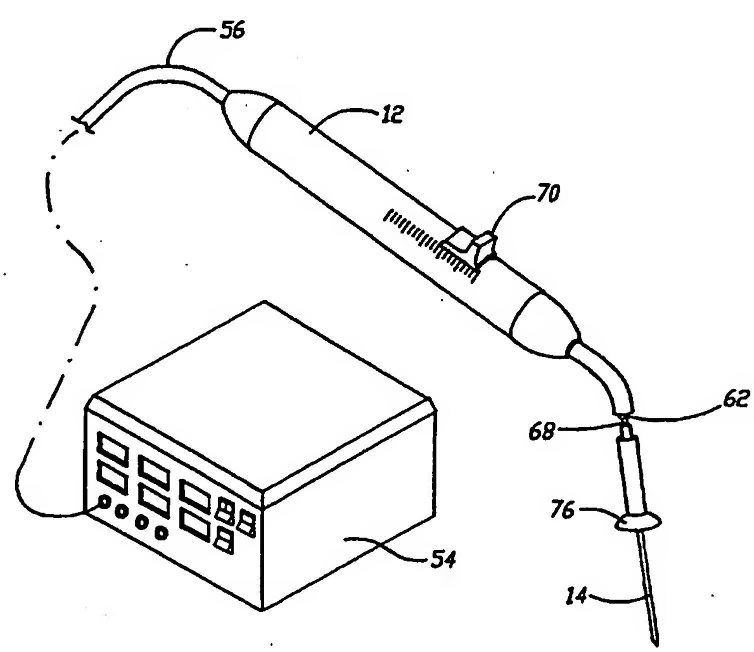

(57) Abstract

A cell necrosis is used to reduce a volume of a selected site of an anatomical structure. An energy delivery device is coupled to a distal portion of a handpiece. The energy delivery device has a tissue piercing distal end. A pressure plate is positioned at an exterior of the energy delivery device to prevent excessive penetration of the energy delivery device into the tissue.

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APPARATUS FOR REDUCING TISSUE VOLUMES BY THE USE OF ENERGY

BACKGROUND OF THE INVENTION

Cross-Reference to Related Applications

This application is a continuation in part of U.S. Patent Application No. 08/905,991, filed August 5, 1997, which is a continuation-in-part of U.S. Patent Application No. 08/642,327, filed May 3, 1996, entitled "Method for Treatment of Airway Obstructions", which is in turn a continuation-in-part application of U.S. Patent Application No. 08/606,195, filed February 23, 1996, entitled "Method for Treatment of Airway Obstructions", which cross-references U.S. Patent Application No. 08/516,781, filed August 18, 1995, entitled "Ablation Apparatus and System for Removal of Soft Palate Tissue", having named inventors Stuart D. Edwards, Edward J. Gough and David L. Douglass, which is a continuation-in-part of U.S. Application No. 08/239,658, filed May 9, 1994 entitled "Method for Reducing Snoring by RF Ablation of the Uvula." This application is also related to an Application Serial No. 08/642,053, filed 5/3/96, entitled "Method and Apparatus for Treatment of Air Way Obstructions", all incorporated by reference herein.

Field of the Invention

This invention relates to an apparatus for the treatment of air way obstructions, and more particularly to an apparatus for creating selective cell necrosis in interior sections of selected head and neck anatomical structures of the human body without damaging vital structures.

Description of Related Art

Sleep-apnea syndrome is a medical condition characterized by daytime hypersomnomulence, morning arm aches, intellectual deterioration, cardiac arrhythmias, snoring and thrashing during sleep. It is caused by frequent episodes of apnea during the patient's sleep. The syndrome is classically subdivided into two types. One type, termed "central sleep apnea syndrome", is characterized by repeated loss of respiratory effort. The second type, termed obstructive sleep apnea syndrome, is characterized by repeated apneic episodes during sleep resulting from obstruction of the patient's upper

airway or that portion of the patient's respiratory tract which is cephalad to, and does not include, the larynx.

Treatment thus far includes various medical, surgical and physical measures. Medical measures include the use of medications such as protriptyline, medroxyprogesterone, acetazolamide, theophylline, nicotine and other medications in addition to avoidance of central nervous system depressants such as sedatives or alcohol. The medical measures above are sometimes helpful but are rarely completely effective. Further, the medications frequently have undesirable side effects and may be contraindicated for some patients.

Surgical interventions have included uvulopalatopharyngoplasty, tonsillectomy, surgery to correct severe retrognathia and tracheostomy. In one type of surgical intervention a standard LeFort I osteotomy is combined with a sagittal split ramus osteotomy to advance the maxilla, mandible and chin. Such a procedure may be effective but the risk of surgery (e.g. morbidity and mortality) in these patients can be prohibitive and the procedures are often unacceptable to the patients.

Physical measures have included weight loss, nasopharyngeal airways, nasal CPAP and various tongue retaining devices used nocturnally. These measures may be partially effective but are cumbersome, uncomfortable and patients often will not continue to use these for prolonged periods of time. Weight loss may be effective but is rarely achieved by these patients.

In patients with central sleep apnea syndrome, phrenic nerve or diaphragmatic pacing has been used. Phrenic nerve or diaphragmatic pacing includes the use of electrical stimulation to regulate and control the patient's diaphragm which is innervated bilaterally by the phrenic nerves to assist or support ventilation. This pacing is disclosed in *Direct Diaphragm Stimulation* by J. Mugica et al. PACE vol. 10 Jan-Feb, 1987, Part II; *Preliminary Test of a Muscular Diaphragm Pacing System on Human Patients* by J. Mugica et al. from Neurostimulation: An Overview 1985, pp. 263-279; and, *Electrical Activation of Respiration* by Nochomovitez IEEE Eng. in Medicine and Biology, June, 1993.

However, it was found that many of these patients also have some degree of obstructive sleep apnea which worsens when the inspiratory force is augmented by the pacer. The ventilation induced by the activation of the diaphragm also collapses the upper airway upon inspiration and draws the patient's tongue inferiorly down the throat choking the patient. These patients then require tracheostomies for adequate treatment.

A physiological laryngeal pacemaker as described in *Physiological Laryngeal Pacemaker* by F. Kaneko et al. from Trans Am Soc Artif Intern Organs, 1985, pp. 293-296 senses volume displaced by the lungs and stimulates the appropriate nerve to open the patient's glottis to treat dyspnea. This apparatus is not effective for treatment of sleep apnea. The apparatus produces a signal proportional in the displaced air volume of the lungs and thereby the signal produced is too late to be used as an indicator for the treatment of sleep apnea. Also, there is often no displaced air volume in sleep apnea due to obstruction.

There are other surgical methods for the treatment of obstructive sleep apnea but they also have medical drawbacks. Tracheostomy, while effective, carries considerable morbidity and is aesthetically unacceptable to many patients. Another surgical procedure involves a standard Le Fort I osteotomy in combination with a sagittal split ramus osteotomy. However, this is a major surgical intervention that requires the advancement of the maxilla, mandible and chin.

Generally, there are two types of snoring. They are distinguished, depending on the localization of their origin. The first type of snoring, velar, is produced by the vibration of all of the structures of the soft palate including the velum, the interior and posterior arches of the tonsils and the uvula. Velar snoring results from a vibration of the soft palate created by the inspiratory flow of air, both nasal and oral, which makes the soft palate wave like a flag. The sound intensity of these vibrations is accentuated by the opening of the buccal cavity which acts as a sound box.

The second type, pharyngeal snoring, is a kind of rattle, including even horn whistling. It is caused by the partial obstruction of the oropharyngeal isthmus by the base of the tongue with, now and again, its total exclusion by the tongue base becoming jammed against the posterior wall of the pharynx. This results in a sensation of breathing, apnea, which constitutes the sleep apnea syndrome. These two types of snoring may easily be combined in the same individual.

For some years there have been surgical techniques for correcting apnea. However, maxillary surgery to cure pharyngeal snoring requires major surgery, with the operation lasting several hours, and the uvula-palatopharnygoplasty procedure to correct velar snoring is not without draw backs. This explains the popularity of prosthesis and other preventive devices.

More recently, portions of the soft palate have been removed by laser ablation; however, there are several limitations to this procedure. First, if too much tissue is

removed, severe consequences result. Also, the degree of laser ablation is difficult to control and multiple treatments are usually required. Finally, patients have a high degree of soreness in their throats for many weeks.

U.S. Patent No. 4,423,812 discloses a loop electrode design characterized by a bare active wire portion suspended between wire supports on an electrode shaft. Tissue striping is performed with a bare wire, that is connected to an electrode shaft insulated to prevent accidental burns to the patient. This allows the physician to use these insulated parts to help position and guide the active wire portion during the surgical procedure. However, this requires that the physician shave off, during multiple procedures, successive thin superficial layers of the obstructing tissues to avoid gross resection and its adverse affects.

U.S. Patent No. 5,046,512 discloses a method for the treatment of snoring and apnea. The method regulates air flow to the user to an extent comparable to the volume of air which flows through the users nasal passages. An associated apparatus provides a device having a body portion sufficiently wide to separate the users teeth. It includes an air passage comparable in area to the area of the user's nasal passages.

The use of oral cavity appliances has been proposed frequently for the treatment of sleep disorders. It has been recognized that movement of the mandible forward relative to the maxilla can eliminate or reduce sleep apnea and snoring symptoms by causing the pharyngeal air passage to remain open. Several intra-oral dental appliances have been developed which the user wears at night to fix the mandible in an anterior protruded position. Such dental appliances essentially consist of acrylic or elastomeric bit blocks, similar to orthodontic retainers or athletic mouth guards, which are custom fitted to a user's upper and lower teeth. The device may be adjusted to vary the degree of anterior protrusion.

U.S. Patent 4,901,737 discloses an intra-oral appliance while reducing snoring which repositions the mandible in an inferior, open, and anterior, protrusive, position as compared to the normally closed position of the jaw. Once the dentist or physician determines the operative snoring reduction position for a particular patient, an appropriate mold is taken for the maxillary dentition and of the mandibular dentition to form an appliance template. This device includes a pair of V-shaped spacer members formed from dental acrylic which extend between the maxillary and mandibular dentition to form a unitary mouthpiece.

While such dental appliances have proven effective in maintaining the mandible in a protruded position to improve airway patency, they often result in undesirable side effects. One of the most common side effects is aggravation of the tempromandibular joint and related jaw muscles and ligaments, especially in individuals who have a tendency to grind their teeth during sleep. Aggravation of the tempromandibular joint has be associated with a wide variety of physical ailments, including migraine headaches. Accordingly, many individuals suffering from sleep apnea and snoring disorders are not able to tolerate existing anti-snoring dental appliances for long periods of time.

Opening of obstructed nasal airways by reducing the size of the turbinates has been performed using surgical and pharmaceutical treatments. Examples of surgical procedures include anterior and posterior ethmoidectomy, such as those described in "Endoscopic Paranasal Sinus Surgery" by D. Rice and S. Schaefer, Raven Press, 1988; the writings of M. Wigand, Messerklinger and Stamberger; and, U.S. Patent No. 5,094,233. The Wigand procedure, described in U.S. Patent No. 5,094,233, involves the transection of the middle turbinate, beginning with the posterior aspect, visualization of the sphenoid ostium and opening of the posterior ethmoid cells for subsequent surgery. In the sphenoidectomy step, the ostium of the sphenoid is identified and the anterior wall of the sinus removed. Following this step, the posterior ethmoid cells may be entered at their junction with the sphenoid and the fovea ethmoidalis can be identified as an anatomical landmark for further dissection. In anterior ethmoidectomy, the exenteration of the ethmoids is carried anteriorly to the frontal recess. Complications, such as hemorrhage, infection, perforation of the fovea ethmoidalis or lamina papyracea, and scarring or adhesion of the middle turbinate, have been reported in connection with these procedures.

One of the problems encountered as a result of these procedures is postoperative adhesion occurring between the turbinates and adjacent nasal areas, such as medial adhesion to the septum and lateral adhesion to the lateral nasal wall in the area of the ethmoid sinuses. Otherwise successful surgical procedures may have poor results in these cases. Some surgeons have proposed amputation of a portion of the turbinate at the conclusion of surgery to avoid this complication, resulting in protracted morbidity (crust formation and nasal hygiene problems). The turbinate adhesion problem detracts from these endoscopic surgical procedures. Efforts have been made to reduce the

complications associated with the surgical treatment of turbinate tissue, for example by the use of a turbinate sheath device. U.S. Patent No. 5,094,233.

U.S. Patent No. 3,901,241 teaches a cryosurgical instrument which is said to be useful for shrinking nasal turbinates. U.S. Patent No. 3,901,241.

Pharmaceuticals have also been developed for reducing the size of the turbinates. However, pharmaceuticals are not always efficacious and generally do not provide a permanent reduction in turbinate size. Additionally, pharmaceuticals can have adverse side effects and are contraindicated for some patients.

Clearly, a medical need exists for a method and device for clearing obstructed nasal passageways. It is preferred that the method and device be performable with minimal surgical intervention or post operative complications. It is also preferred that the method and device reduce the size of the turbinate structure without involving surgical cutting or the physical removal of tissue. It is also preferred that the method and device provide a reduction in turbinate structure size to increase air flow in the nasal passageway sufficiently impairing blood flow to the optic nerve and/or retina and create a permanent impairment of vision by the ablation.

It would be desirable to provide an ablation apparatus which eliminates the need for dental appliances for the treatment of snoring and sleep apnea disorders. It would also be desirable to provide a treatment device which is not an intra-oral dental appliance, and which can effectively and safely remove selected portions of the soft palate without providing the patient with undesirable side effects. Further, it would be desirable to provide a tissue ablation device which creates localized pressure at an electrode introduction tissue site to make it easier for electrode introduction into tissue. It would yet further desirable to provide an ablation apparatus with a safety stop that reduces surface ablation at an electrode introduction tissue site.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide an apparatus for the treatment of obstructed nasal and upper respiratory passage ways through the use of selective cell necrosis at a selected site of different head and neck anatomical structures.

Another object of the invention is to provide an apparatus to treat airway obstructions.

Yet another object of the invention is to provide an ablation apparatus that provides controlled cell necrosis of upper airway anatomical structures.

A further object of the invention is to provide an ablation apparatus that applies localized force at an electrode tissue introduction site.

Still another object of the invention is to provide an ablation apparatus that minimizes surface cell necrosis at an energy delivery device tissue introduction site.

These and other objects of the invention are achieved in a cell necrosis apparatus to reduce the volume of a selected site of an anatomical structure. An energy delivery device is coupled to a distal portion of a handpiece. The energy delivery device has a tissue piercing distal end. A pressure plate is positioned at an exterior of the energy delivery device and a cable is coupled to the energy delivery device.

In another embodiment, a cell necrosis apparatus includes a handpiece and an energy delivery device coupled to a distal portion of the handpiece. A safety stop is positioned at an exterior of the energy delivery device. A cable is coupled to the energy delivery device.

In yet another embodiment, An apparatus to reduce a volume of a selected site in an interior of an anatomical structure includes an introducer. An energy delivery device is at least partially positionable in the interior of the introducer. A pressure plate is positioned at an exterior of the introducer and a cable is coupled to the energy delivery device.

In still a further embodiment, an advancement member is coupled to the energy delivery device.

In still yet another embodiment, an infusion lumen in the energy delivery device is coupled to medicinal solutions, irrigating solutions electrolyte solutions, contrast media and disinfectants via a disinfectant medium introduction member.

BRIEF DESCRIPTION OF THE FIGURES

Figures 1A-B illustrate lateral view of the oral cavity and the positioning of the cell necrosis apparatus of the present invention in the oral cavity.

Figure 1C depicts a lateral view of the oral cavity illustrating the repositioning of the tongue following treatment.

Figures 2A-B illustrate front and side perspective views of the pressure plate shown in Figures 1A-C.

Figures 3A-3B illustrate the creation of various cell necrosis zones.

Figure 4 illustrates the introduction of fluids into the necrosis zone using a multi aperture hollow energy delivery device.

Figure 5 illustrates the introduction of boluses solution to tissue.

Figure 6A illustrates a perspective view of the cell necrosis apparatus of the present invention coupled to an energy source.

Figure 6B illustrates a close up cross-sectional view of a hollow energy delivery device of the invention utilized to create a cell necrosis zone below a tissue surface.

Figure 7 illustrates a cross-sectional view of the distal end of the energy delivery device of Figure 6B.

Figure 8 illustrates a cross-sectional view of the hollow energy delivery device with a sealing plug to control fluid flow.

Figure 9 illustrates the creation of cell necrosis zones in the uvula and the repositioning of the uvula in the oral cavity.

Figure 10 illustrates the creation of cell necrosis zones in the turbinates and the repositioning of the turbinates in the nasal cavity.

Figure 11 illustrates a cross-sectional view of the arteries of the nasal cavity.

Figure 12 depicts a cross-sectional view of the head illustrating the arteries of the nasal cavity.

Figure 13 depicts a cross-sectional view of the head taken laterally through the nasal cavity illustrating a shrinkage of the turbinates following treatment with the cell necrosis apparatus of the present invention.

Figure 14 depicts a close up cross-sectional view of Figure 13.

Figure 15 depicts a cross-sectional view of the head illustrating the creation of cell necrosis zones in the soft palate structure.

Figure 16 depicts a cross-sectional view of the soft palate structure of Figure 15 illustrating the repositioning of the soft palate structure following creation of the cell necrosis zones.

Figure 17A is a perspective view of an embodiment of the present invention with the pressure plate positioned at an exterior of an introducer.

Figure 17B depicts a perspective and cross sectional view of the distal tip of the introducer.

Figure 17C is an enlarged view of the distal tip of the energy delivery device.

Figure 17D depicts the flow path between the cell necrosis apparatus and the infusion fluid reservoir.

Figure 18 depicts a block diagram of the feed back control system that can be used with the cell necrosis apparatus as shown in Figures 1A-C.

Figure 19 depicts a block diagram of an analog amplifier, analog multiplexer and microprocessor used with the feedback control system of Figure 19.

Figure 20 depicts a block diagram of the operations performed in the feedback control system depicted in Figure 18.

DETAILED DESCRIPTION

Referring now to Figures 1A-C, a cell necrosis apparatus 10 is used to reduce the volume of a selected site in an interior of a head and neck structure, and more particularly to a structure that is associated with an airway passage. Suitable anatomical structures include but are not limited to the tongue, uvula, soft palate tissue, tonsils, adenoids, turbinate structures and the like. In Figures 1A-C, cell necrosis apparatus 10 is shown as including a handpiece 12 coupled to an energy delivery device 14.

It will be appreciated that although the term "energy delivery device" in includes but is not limited to a device for the delivery of electromagnetic energy such as RF, microwave and optical energy; a device for the delivery of acoustical energy such as ultrasonic energy; a device for the delivery of a thermal liquid jet; and, a device for performing resistance heating. The preferred energy source is an RF source and electrode 14 is an RF electrode operated in either bipolar or monopolar mode with a ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode 14 is used in combination with an indifferent electrode patch that is applied to the body to form the other contact and complete an electrical circuit. Bipolar operation is possible when two or more electrodes 14 are used. Multiple electrodes 14 may be used.

When the energy source is RF, an RF energy source may have multiple channels, delivering separately modulated power to each electrode 14. This reduces preferential heating that occurs when more energy is delivered to a zone of greater conductivity and less heating occurs around electrodes 14 which are placed into less conductive tissue. If the tissue hydration or blood infusion in the tissue is uniform, a single channel RF energy source may be used to provide power for the treatment of cell necrosis zones relatively uniform in size.

Handpiece 12 can be a proximal portion of energy delivery device 14 that is suitably configured to enable placement and removal of cell necrosis apparatus to and from a selected anatomical structure and may include, in one embodiment, a proximal portion of energy delivery device 14 that is insulated. A pressure plate 15 can be positioned on an exterior surface of energy delivery device 14. Pressure plate 15

includes a tissue interface surface 17 which can include all of a portion of the indicated surface depending on the amount of contact between the anatomical structure surface and tissue interface surface 17 which may be dependent on the amount of force applied to the surface of the anatomical structure.

Handpiece 12 and energy delivery device 14 are sized and of a suitable geometry to be maneuverable in an oral cavity 16, pierce a tongue surface 18 and advance into an interior 20 of a tongue 22 a sufficient distance 24 to a tissue site 26. Another embodiment of pressure plate 15 is as a safety stop such that depth of tissue penetration of energy delivery device 14 is controlled by pressure plate 15. Electromagnetic energy is delivered to tissue site 26 to create cell necrosis at zone 28 without damaging a main branch of the hypoglossal nerve. A cable 30 is coupled to energy delivery device 14. For purposes of this disclosure, the main branches of the hypoglossal nerve are those branches which if damaged create an impairment, either partial or full, of speech or swallowing capabilities. As shown in Figure 1C, the treated structure of tongue 22 is repositioned in oral cavity 16. With this cell necrosis, the back of the tongue 22 moves in a forward direction (as indicated by the arrow) away from the air passageway. The result is an increase in the cross-sectional diameter of the air passageway.

Handle 14 is preferably made of an electrical and thermal insulating material. When energy delivery device 14 is an electrode, the electrode can be made of a conductive material such as stainless or a shaped memory metal, such as Nitinol (a nickel titanium alloy), commercially available from Raychem Corporation (Menlo Park, California) as well as numerous other companies. In one embodiment, only a distal end of electrode 14 is made of the shaped memory metal in order to effect a desired deflection.

Cell necrosis apparatus 10 can include visualization capability including but not limited to a viewing scope, an expanded eyepiece, fiber optics, video imaging, and the like.

Energy delivery device 14 can include an insulator 32 which can be adjustable in length and in a surrounding relationship to an exterior surface of energy delivery device 14. Insulator 32 serves as a barrier to thermal or RF energy flow. Insulator 32 can be in the form of an sleeve that may be adjustably positioned at the exterior of energy delivery device 14. In one embodiment insulator can be made of a polyamide material and be a 0.002 inch shrink wrap. The polyamide insulating layer is semi-rigid.

That portion of energy delivery device 14 which is not insulated is an energy delivery surface 33.

Handpiece 12 can have a reduced diameter at a distal portion 34 to facilitate positioning, maneuverability, provide easier access to smaller openings and improve the visibility in the area where energy delivery device 14 is to penetrate.

To use cell necrosis apparatus 10 in oral cavity 16, a topical and then a local anesthetic is applied to tongue 22. After a suitable period for the anesthesia to take effect, the physician may grasp the body of tongue 22 near the apex, using a gauze pad for a better grip. Tongue 22 is then drawn forward, bringing the body and the root of tongue 22 further forward for improved accessibility. Grasping handpiece 12, the physician positions a distal portion of energy delivery device 14 at tongue surface 18. The position of energy delivery device 14 in Figures I A-C illustrates cell necrosis zone 28 below a mucosal surface 36 providing a protected zone 38. An insulated portion 40 of energy delivery device 14 prevents delivery of energy to a main branch of a hypoglossal nerve and/or to mucosal surface 36.

Energy delivery device 14 can have an angle 42 at a bend zone 44 which is lateral to a longitudinal axis of handpiece 12. Energy delivery device 14 can be malleable to create different bend zones, depending on the anatomical structure and the insertion position of the anatomical structure. With the use of a bending fixture, not shown, the arc of angle 42 can be adjusted by the physician as needed at the time of treatment.

One or more sensors 46 can be included and positioned at a distal end of energy delivery device 14, at a distal end of insulator 32, as well as at other positions of cell necrosis apparatus 10. Sensor 46 is of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. Suitable sensors that may be used for sensor 46 include: thermocouples, fiber optics, resistive wires, thermocouple IR detectors, and the like. Suitable thermocouples for sensor 46 include: T type with copper constantene, J type, E type and K types.

Energy delivery device 14 can experience a steep temperature gradient as current moves outward through the energy delivery device 14. This causes the tissue that is immediately adjacent to energy delivery device 14 to reach temperatures of 100 degrees C or more while tissue only 5 to 10 mm away may be at or near body temperature. Because of this temperature gradient, it is often necessary to position energy delivery device 14 several times at the intended insertion site or use a plurality of

energy delivery devices 14 to create a cell necrosis zone 28 of the desired volume. Because of the aggressive heating immediately proximal of energy delivery device 14 desiccation of tissue adjacent to energy delivery device 14 may result. When the fluid within the tissue is desiccated, no electrical current flows through the tissue and the heating is then terminated. This problem can be solved by using lower energy delivery rates (e.g. power) to energy delivery device 14, in turn reducing the rate of temperature increase in adjacent tissue. This solution requires extended treatment periods.

Referring now to Figures 2A and 2B, pressure plate 15 has an exterior geometry section selected from a planar surface, a curved surface, a concave surface, a convex surface and combinations thereof. One embodiment is a convex curved shape, including hemispherical in order to minimize trauma to tissue adjacent to the tissue insertion site. Pressure plate 15 will also have an aperture for the advancement and retraction of electrode 14. The preferred planar geometry of pressure plate 15 is circular. The preferred tissue contact surface area of pressure plate 15 is between 0.005 to 0.250 inches. Pressure plate 15 will also be made of an electrically non-conductive material in order to electrically isolate tissue insertion site from all sources of electrical current other than that delivered by energy delivery device 14. Tissue interface surface 17 applies a force to energy delivery device insertion site of the anatomical structure. This force can compress and/or immobilize the tissue at the energy delivery device insertion site to facilitate a penetration of the energy delivery device 14 into the anatomical structure. Pressure plate 15 can be adjustably mounted on an exterior of energy delivery device 14. Pressure plate can be configured to allow the advancement and retraction of the energy delivery device 14. Pressure plate 15 can be positioned against the tongue, uvula, soft palate, tonsils and turbinate in order to facilitate entry of energy device 14 into the interior of each structure with minimal trauma to surface tissue.

Figures 3A and 3B illustrate cell necrosis zones 28 and insulator 32 in greater detail. Referring now to Figure 4, an embodiment of the invention is disclosed where energy delivery device 14 includes a hollow lumen 48 and a plurality of apertures through which a fluid medium can flow. Suitable fluid mediums include but are not limited to cooling and heating fluids, electrolytic solutions, chemical ablation medium, a disinfectant medium and the like.

A suitable electrolytic solution is saline, solutions of calcium salts, potassium salts, and the like. Electrolytic solutions enhance the electrical conductivity of the

tissue. When a highly conductive fluid is infused into tissue, the electrical resistance is reduced and the electrical conductivity of the infused tissue is increased. With this condition there will be little tendency for tissue surrounding energy delivery device 14 to desiccate and the result is a large increase in the capacity of the tissue to carry RF energy. A zone of tissue which has been heavily infused with a concentrated electrolytic solution can then become so conductive as to actually act as an electrode. The effect of the larger (fluid) electrode is that greater amounts of current can be conducted, making it possible to heat a much greater volume of tissue in a given time period.

In addition to the larger electrode area that results from infusion of an electrolytic solution it is then possible to inject one or more boluses 50 of electrolytic solution as shown in Figure 5. RF current 52 can then flow through the infused tissue surrounding electrode 14 and follow the course of least electrical resistance into the infused tissue of the neighboring bolus.

By placing the injections of electrolytic solution according to the need for thermal tissue damage, a single electrode 14 may deliver heating to a large volume of tissue and the shape of cell necrosis zone 28 created may be placed to create cell necrosis in exactly the area desired. This simplifies the control of cell necrosis zone 28 generation and allows the physician to produce larger lesions in a brief session.

Additionally, the conductivity of the injected electrolytic solution can be decreased. While the advantages of avoiding desiccation adjacent to electrode 14 are maintained, higher electrical resistance is encountered in the infused tissue. This results in greater heating in the tissue closer to electrode 14. Varying the electrical conductivity of the infused tissue can be used to adjust the size of cell necrosis zone 28 and control the extent of thermal damage.

Disinfectant mediums can also be introduced through energy delivery device 14. Suitable disinfectant mediums include but are not limited to Peridex, an oral rinse containing 0.12% chlorhexidine glucinate (1, 1'-hexanethylenebis[5-(p-chlorophenyl) biganide) di-D-gluconate in a base containing water, 11.6% alcohol, glycerin, PEG 40 sorbitan arisoterate, flavor, dosium saccharin, and FD&C Blue No. 1. The disinfectant medium can be introduced prior to, during and after cell necrosis.

Referring now to Figures 6 through 8, energy delivery device 14 may include hollow lumen 48 that is in fluid communication with a control unit 54 which controls the delivery of the fluid via a conduit 56 configured to receive a cooling or heating

solution. All of only a portion of a distal portion 14' of energy delivery device 14 is cooled or heating.

The introduction of a cooling fluid reduces cell necrosis of surface layers without the use of insulator 32. This preserves surface mucosal and/or epidermal layers as well as protects a tissue site in the vicinity or in cell necrosis zone 28 from receiving sufficient energy to cause cell necrosis. For instance, it may be desirable to insert energy delivery device 14 into an organ in a position which is adjacent to, or even within, some feature that must be preserved while treating other areas including but not limited to blood vessels, nerve bundles, glands and the like. The use of cooling permits the delivery of thermal energy in a predetermined pattern while avoiding heating critical structures.

A sealing plug 58 may be positioned in hollow energy delivery device 14 and used to determine the length of energy delivery device 14 that receives the cooling fluid. Sealing plug 58 can include one or more sealing wipers 60 positioned on an outer diameter of sealing plug 50. A fluid tube 62 is coupled to a proximal portion of sealing plug 58 and positioned adjacent to the proximal surface of sealing plug 58. A plurality of fluid distribution ports 64 are formed in fluid tube 62. Cooling fluid, which may be a saline solution or other biologically compatible fluid, is fed from control unit 54 through a small diameter dual lumen tube positioned in conduit 56. Cooling fluid flows through fluid tube 62 to the most distal end where it exits through fluid distribution ports 64 arranged about the outer diameter of fluid tube 62. Cooling fluid then flows within hollow lumen 48 and is in direct contact with the wall structure of energy delivery device 14, which is typically metallic and provides a highly efficient heat transfer. Cooling fluid flows to the proximal end of energy delivery device protected a 14 and through the second lumen of the fluid tube 62, then to control unit 54 which includes both a supply reservoir and a return reservoir to catch and retain the used cooling fluid.

Energy delivery device 14 may have one or more sensors 46 for sensing the temperature of the tissue. This data is fed back to control unit 54 and through an algorithm is stored within a microprocessor memory of control unit 54. Instructions are sent to an electronically controlled micropump (not shown) to deliver fluid through the fluid lines at the appropriate flow rate and duration to provide control of tissue temperature.

The reservoir of control unit 54 may have the ability to control the temperature of the cooling fluid by either cooling the fluid or heating the fluid. Alternatively, a fluid

reservoir of sufficient size may be used in which the cooling fluid is introduced at a temperature at or near that of the normal body temperature. Using a thermally insulated reservoir, adequate control of the tissue temperature may be accomplished without need of refrigeration or heating of the cooling fluid.

Cooling zone 66 is adjustable in size and location by moving sealing plug 58 using a stylet 68 which is controlled by a slider 70 position at handpiece 12. In this manner, the position of cooling zone 66 can be moved along the length of energy delivery device 14 and the area which is cooled is then proximal of sealing plug 58. In the event it is desirable to have cooling zone 66 within a length of energy delivery device 14 then a second sealing plug 58 can be positioned at a distance proximal of the first or distal sealing plug 58 and the cooling fluid then re-enters the second lumen of fluid tube 62 at proximal sealing plug 58. The distance between the two sealing plugs 58 determines the length of cooling zone 66. In this example, the distal and proximal sealing plugs 58 move together when activated by stylet 68, re-positioning cooling zone 66.

In another embodiment, the distal and proximal sealing plugs 58 are adjusted individually. This provides the ability to both change the position and length of cooling zone 66.

In typical use, cooling zone 66 is positioned so that a predetermined thickness of mucosal or epidermal tissue 72 on the surface of the tissue to be treated 74 is protected as indicated at 75 while the desired cell necrosis zone 28 is formed.

An alternative feature is the ability to indicate to the physician the amount of energy delivery device 14 length that is inserted into the tissue and the depth of protected area 32. To accomplish this, a portion of cell necrosis apparatus 10 comes in contact with mucosal or epidermal surface 72. This can be achieved with a contact collar 76 or with a larger surface that is contoured to fit against the organ or anatomical feature to be treated. The dimensional relationship between contact collar 76 and handpiece 12 is maintained by a sleeve 78 through which energy delivery device 14, fluid tube 62 and stylet 68 all pass. With this dimensional relationship maintained, it is then possible to indicate with indexing pointers on handpiece 12 the distance of energy delivery device 14 distal of contact collar 76 or the surface of cell necrosis apparatus 10. The distance of cooling zone 66 is then positioned distal of contact collar 76 or the surface cell necrosis apparatus 10. Because all cooling is within energy delivery device

14 and external insulator 32 is not used, energy delivery device 14 penetrates easily through the tissue without drag or resistance that is present when insulator 32 is present.

In another embodiment, sealing plugs 58 and direct flow of cooling fluid are replaced with a slidable inner cooling plug which may be constructed of a material with efficient heat transfer characteristics. Suitable cooling plug materials include but are not limited to copper, beryllium copper, silver and aluminum alloys. Cooling plug is sized to fit intimately against the inner surface of needle 14. This allows transfer of heat from energy delivery device 14 to cooling the plug. In this embodiment, cooling plug has interior passageways through which cooling fluid passes. This draws heat from the cooling plug.

Although this embodiment does not provide the highly efficient cooling available by having the cooling fluid in direct contact with the inner surface of energy delivery device 14, a more thorough isolation of the cooling fluid from the body is provided. This results from reducing the possibility of experiencing some leakage past sealing plug 58 of the other embodiment.

In yet another embodiment of cooling, heat pipe technology is used. A sealed compartment contains a mixture of gases which have the ability to rapidly vaporize and condense at temperatures which facilitate the transfer of heat with high efficiency. In this embodiment, a cooling module within handpiece 12 cools the proximal end of the tubular heat pipe and heat is conducted from cooling zone 66 to the cooling module.

Cell necrosis apparatus 10 can be used to create cell necrosis in other structures that affect airway passages including but not limited to the uvula, turbinate structures, soft palate structures and tonsils.

As shown in Figure 9, cell necrosis apparatus 10 is used to create one or more cell necrosis zones 28 in uvula 80. Energy delivery device 14 is configured to be maneuverable in oral cavity 16, pierce an uvula exterior surface, advance into an interior of the uvula a sufficient distance 84 to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis. The creation of cell necrosis zones 28 repositions the treated uvula 80 in oral cavity 16 (as indicated by the arrows) while substantially preserving an uvula mucosal layer 82 at an exterior of uvula 80. Cell necrosis zones 28 are created in uvula 80 without creating an ulceration line at a tip 86 of uvula 80. Controlled cell necrosis tightens and reshapes uvula 80.

In creating uvula 80, energy delivery device 12 can have a variety of geometric configurations and may include a curved distal end. The different cell necrosis zones 28

can be stacked in one or more treatment sessions. This permits the physician to control the amount of tissue treated and to assess the results of each session before proceeding with additional procedures. Because exterior mucosal tissue is spared, the patient experiences little pain or discomfort.

Referring now to Figure 10, cell necrosis apparatus 10 is used to create cell necrosis zones 28 in a turbinate structure 88, which can include the interior nasal concha, the middle nasal concha, the superior nasal concha, and combinations thereof. Energy delivery device 14 is configured to be maneuverable in a nostril, pierce a turbinate structure surface 90 advance into an interior of turbinate structure 88 a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site and create controlled cell necrosis of turbinate structure 88 to increase the size of a nasal passageway 90.

Sufficient electromagnetic energy is delivered to the tissue site to create controlled cell necrosis of the turbinate structure without sufficiently limiting blood flow to the optic nerve and/or the retina (Figure 11). As shown in Figure 12 disruption of the blood flow to the optic nerve and/or retina can sufficiently damage the optic nerve and/or retina and create a permanent impairment of vision.

Referring to Figure 10, energy delivery device 14 creates cell necrosis zones 28 to reduce the size turbinate structure 88 by removing only so much of turbinate structure 88 to increase the size of the nasal passageway but insufficient to create a permanent, (i) dysosmic state, (ii) dry nose condition, (iii) atrophic rhinitis state, (iv) a loss of ciliary function or (v) damage to the nerves of nasal cavity creating a permanent loss of nasal and facial structure activity. The creation of the ablation zones in turbinate structure 88 repositions turbinate structure 88. In one embodiment, no more than 33% of the mucosal layer of the lower turbinate is removed. Further removal may create the dysosmic state, a permanent dry nose condition and/or a loss of ciliary function.

As illustrated in Figures 13 and 14, cell necrosis apparatus 10 provides controlled ablation of turbinate structures 88 and the resulting turbinate structure is repositioned in the nasal cavity, and can "open up" the nasal cavity for allergy sufferers and the like. Pressure plate 15 is positioned against desired turbinate to facilitate entry of energy delivery device into tissue to reach necrosis site 92.

In another embodiment, cell necrosis apparatus 10 reduces a volume of a selected site in an interior of a soft palate structure 94 (refer to Figures 15 and 16).

Energy delivery device 14 is configured to be maneuverable in oral cavity 16, pierce a soft palate structure surface 96, advance a sufficient distance to a tissue site, deliver electromagnetic energy to the tissue site, create controlled cell necrosis zones 28 and reposition soft palate structure 94 in oral cavity 16 with reduced necrosis of an exterior mucosal surface 98 of soft palate structure 94. The creation of cell necrosis zones 28 repositions soft palate structure 94 and tightens the interior tissue of soft palate structure as illustrated by the arrows.

Referring now to Figures 17A, 17B, 17C, and 17D an embodiment of cell necrosis apparatus 100 is illustrated where energy delivery device 114 is at least partially positionable in an introducer 102 coupled to handpiece 112 and pressure plate 115 is positionable on an exterior surface of introducer 102. Pressure plate 115 includes a tissue interface surface 117.

One or more energy delivery devices 114 can extend from different ports formed along an exterior surface of introducer 102. Introducer 102 can also be the same as handpiece 112. An energy delivery device advancement device 104 may be provided, although in various embodiments with introducer 102 one is not necessary. Energy delivery device advancement device 104 can include guide tracks or tubes 106 positioned in the interior of introducer 102. Energy delivery devices 114 may be positioned in guide tracks 106 and advanced from the guide tracks 106 into the interior of the anatomical structure. Cabling is coupled to energy delivery devices 114. Introducer 102 and handpiece 112 may be one device. Pressure plate 115 can also be positioned at a distal portion of the introducer 102. A second energy delivery device 114 can be coupled to a second introducer 102 coupled to the handpiece. Similarly a second pressure 115 can be positioned at an exterior of the second introducer 102.

A disinfectant medium introduction member 108 can be coupled to cell necrosis apparatus 100 either in an interior or at an exterior. Disinfectant medium introduction member 108 may be slidably positioned in introducer 102 or at its exterior. Alternatively, disinfectant medium introduction member 108 can be an optical fiber coupled to a light energy source. Disinfection medium introduction member can be coupled to infusion fluid reservoir 111 (see figure 17D).

Energy delivery devices 114 are at least partially positioned in an interior of introducer 102. Each energy delivery device 114 can be advanced and retracted through a port 109 formed at a distal end or along a side of introducer 102. Energy delivery devices 114 can be hollow to receive a variety of different infusion fluids, including

medicinal solutions, electrolyte solutions, irrigation solutions and contrast media. This is accomplished by coupling energy delivery device 114 to infusion fluid reservoir 111 through energy delivery device advancement device 104 (see figure 17D).

Introducer 102 includes a temperature control medium conduit 111 that can extend through an interior of introducer 102. The depth of tissue penetration of energy delivery device 114 is controlled by pressure plate 115.

An energy delivery surface 133 of energy delivery device 114 can be adjusted by inclusion of an adjustable or non-adjustable insulation sleeve 132. Insulation sleeve 132 can be advanced and retracted along the exterior surface of energy delivery device 114 in order to increase or decrease the length of energy delivery surface 133.

Introducer 102 can be malleable. A soft metal member may be enclosed or encapsulated within a flexible outer housing to form a malleable introducer 102.

In another embodiment, handpiece 112 is conformable or deflectable. This can be achieved mechanically or with the use of shape memory metals. A steering wire, or other mechanical structure, can be attached to either the exterior or interior of a distal end of introducer 102. In one embodiment, a deflection knob (not shown) located on handpiece 112 is activated by the physician causing a steering wire to tighten (not shown). This imparts a retraction of the distal end of introducer 102. It will be appreciated that other mechanical devices can be used in place of the steering wire. The deflection may be desirable for tissue sites with difficult access.

Energy delivery devices 114 can be spring loaded. When energy delivery device advancement device 104 is moved back, springs cause selected energy delivery devices 114 to advance out of introducer 102.

One or more sensors 146 may be used to measure temperatures. One or more sensors 146 may be positioned on an interior or exterior surface of energy delivery device 114, insulation sleeve 132, or be independently inserted into the interior of the anatomical structure.

Cell necrosis apparatus 100 can include visualization capability including but not limited to a viewing scope, ultrasound, an expanded eyepiece, fiber optics, video imaging, and the like.

Additionally, an ultrasound transducer 116 can determine the size and position of the created lesion. In one embodiment, two ultrasound transducers 116 are positioned on opposite sides of introducer 102 to create an image depicting the lesion in

the anatomical structure. Each ultrasound transducer 116 is coupled to an ultrasound source (not shown).

In one embodiment, cell necrosis apparatus 100 is coupled to an open or closed loop feedback system. Referring now to Figure 18, an open or closed loop feedback system couples sensor 346 to energy source 392. In this embodiment, energy delivery device 314 is one or more RF electrodes 314.

The temperature of the tissue, or of RF electrode 314 is monitored, and the output power of energy source 392 adjusted accordingly. Additionally, the level of disinfection in the oral cavity can be monitored. The physician can, if desired, override the closed or open loop system. A microprocessor can be included and incorporated in the closed or open loop system to switch power on and off, as well as modulate the power. The closed loop system utilizes a microprocessor 394 to serve as a controller, monitor the temperature, adjust the RF power, analyze at the result, refeed the result, and then modulate the power.

With the use of sensor 346 and the feedback control system a tissue adjacent to RF electrode 314 can be maintained at a desired temperature for a selected period of time without impeding out. Each RF electrode 314 is connected to resources which generate an independent output. The output maintains a selected energy at RF electrode 314 for a selected length of time.

Current delivered through RF electrode 314 is measured by current sensor 396. Voltage is measured by voltage sensor 398. Impedance and power are then calculated at power and impedance calculation device 400. These values can then be displayed at user interface and display 402. Signals representative of power and impedance values are received by a controller 404.

A control signal is generated by controller 404 that is proportional to the difference between an actual measured value, and a desired value. The control signal is used by power circuits 406 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at respective RF electrodes 314.

In a similar manner, temperatures detected at sensor 346 provide feedback for maintaining a selected power. Temperature at sensor 346 is used as a safety means to interrupt the delivery of energy when maximum pre-set temperatures are exceeded. The actual temperatures are measured at temperature measurement device 408, and the temperatures are displayed at user interface and display 402. A control signal is generated by controller 404 that is proportional to the difference between an actual

measured temperature and a desired temperature. The control signal is used by power circuits 406 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at the sensor 346. A multiplexer can be included to measure current, voltage and temperature, at the sensor 346, and energy can be delivered to RF electrode 314 in monopolar or bipolar fashion.

Controller 404 can be a digital or analog controller, or a computer with software. When controller 404 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus is a program memory and a data memory.

User interface and display 402 includes operator controls and a display. Controller 404 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

The output of current sensor 396 and voltage sensor 398 is used by controller 404 to maintain a selected power level at RF electrode 314. The amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 404 and a preset amount of energy to be delivered may also be profiled.

Circuitry, software and feedback to controller 404 result in process control, and the maintenance of the selected power setting that is independent of changes in voltage or current, and used to change, (i) the selected power setting, (ii) the duty cycle (on-off time), (iii) bipolar or monopolar energy delivery and (iv) fluid delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensor 346.

Referring to Figure 19, current sensor 396 and voltage sensor 398 are connected to the input of an analog amplifier 410. Analog amplifier 410 can be a conventional differential amplifier circuit for use with sensor 346. The output of analog amplifier 410 is sequentially connected by an analog multiplexer 406 to the input of A/D converter 408. The output of analog amplifier 410 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 408 to microprocessor 394. Microprocessor 394 may be a type 68HCII available from Motorola. However, it will be appreciated that any suitable

microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 394 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 394 corresponds to different temperatures and impedances.

Calculated power and impedance values can be indicated on user interface and display 402. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 394 with power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 402, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 394 can modify the power level supplied by energy source 392.

Figure 20 illustrates a block diagram of a temperature/impedance feedback system that can be used to control temperature control fluid flow rate through introducer 102. Energy is delivered to RF electrode 314 by energy source 392, and applied to tissue site 424. A monitor 416 ascertains tissue impedance, based on the energy delivered to tissue, and compares the measured impedance value to a set value. If the measured impedance exceeds the set value, a disabling signal 412 is transmitted to energy source 392, ceasing further delivery of energy to electrode 314. If measured impedance is within acceptable limits, energy continues to be applied to the tissue. During the application of energy sensor 346 measures the temperature of tissue and/or electrode 314. A comparator 420 receives a signal representative of the measured temperature and compares this value to a pre-set signal representative of the desired temperature. Comparator 420 sends a signal to a flow regulator 422 representing a need for a higher temperature control fluid flow rate, if the tissue temperature is too high, or to maintain the flow rate if the temperature has not exceeded the desired temperature.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. A cell necrosis apparatus to treat a selected site of an anatomical structure, comprising:

a handpiece;

an energy delivery device coupled to a distal portion of the handpiece including a tissue piercing distal end;

a pressure plate positioned at an exterior of the energy delivery device; and

a cable coupled to the energy delivery device.

2. The apparatus of claim 1, wherein the apparatus reduces a volume of the selected site of the anatomical structure.

3. The apparatus of claim 1, wherein the apparatus alters a shape of the anatomical structure.

4. The apparatus of claim 1, wherein the energy delivery device is an RF electrode.

5. The apparatus of claim 4, further comprising:

an RF energy source coupled to the RF electrode.

6. The apparatus of claim 1, wherein the energy delivery device is a microwave antenna.

7. The apparatus of claim 6, further comprising:

a microwave energy source coupled to the microwave antenna.

8. The apparatus of claim 1, wherein the energy delivery device is a waveguide.

9. The apparatus of claim 8, further comprising:

a light source coupled to the waveguide.

10. The apparatus of claim 9, wherein the light source is a laser.

11. The apparatus of claim 1, wherein the energy delivery device is an acoustical transducer.

12. The apparatus of claim 1 1, further comprising:
an acoustical energy source coupled to the acoustical transducer.

13. The apparatus of claim 1, wherein the energy delivery device is a resistive heating device.

14. The apparatus of claim 13, further comprising:
an electrical current source coupled to the resistive heating device.

15. The apparatus of claim 1, further comprising:
a second energy delivery device coupled to the handpiece.

16. The apparatus of claim 15, further comprising: a second pressure plate positioned at an exterior of the second energy delivery device.

17. The apparatus of claim 1, wherein the energy delivery device includes an infusion lumen.

18. The apparatus of claim 17, wherein the infusion lumen is coupled to a medication source.

19. The apparatus of claim 17, wherein the infusion lumen is coupled to a contrast medium source.

20. The apparatus of claim 17, wherein the infusion lumen is coupled to a electrolytic solution source.

21. The apparatus of claim 17, wherein the infusion lumen is coupled to a disinfectant source.

22. The apparatus of claim 1, further comprising:
a cooling device coupled to the energy delivery device.

23. The apparatus of claim 1, further comprising:
an insulator positioned at an exterior of the energy delivery device.

24. The apparatus of claim 1, further comprising:
a sensor coupled to the energy delivery device.

25. The apparatus of claim 24, wherein the sensor is positioned at a distal portion of the energy delivery device.

26. The apparatus of claim 1, further comprising:
a feedback control system coupled to the energy delivery device, a sensor and an energy source.

27. The apparatus of claim 1, wherein the pressure plate defines a depth of penetration of the energy delivery device in the anatomical structure.

28. The apparatus of claim 1, wherein the pressure plate defines an area of an energy delivery surface of the energy delivery device.

29. The apparatus of claim 1, wherein the pressure plate includes a tissue interface surface.

30. The apparatus of claim 1, wherein the pressure plate has a an exterior geometry section selected from a planar surface, a curved surface, a concave surface, a convex surface and combinations thereof.

31. The apparatus of claim 29, wherein the tissue interface surface applies a force to an energy delivery device insertion site of the anatomical structure.

32. The apparatus of claim 31, wherein the force immobilizes the tissue at the energy delivery device insertion site to facilitate a penetration of the energy delivery device into the anatomical structure.

33. The apparatus of claim 31, wherein the force creates a compression of the energy delivery device insertion site to facilitate a penetration of the energy delivery device into the anatomical structure.

34. The apparatus of claim 29, wherein an area of the tissue interface surface is in the range of 0.005 to 0.25 in^2.

35. The apparatus of claim 1, wherein the pressure plate is adjustably mounted on an exterior of the energy delivery device.

36. The apparatus of claim 1, wherein the pressure plate is configured to allow the advancement and retraction of the energy delivery device.

37. The apparatus of claim 36, wherein the pressure plate includes an aperture for the advancement and retraction of the energy delivery device through the pressure plate.

38. The apparatus of claim 1, wherein the pressure plate is made of a nonconductive material.

39. The apparatus of claim 38, wherein the pressure plate provides electrical isolation at the tissue insertion site from the cell necrosis apparatus.

40. The apparatus of claim 1, wherein the anatomical structure is selected from a tongue, a turbinate, an uvula, a soft palate, and a tonsil.

41. A cell necrosis apparatus to treat a selected site of an anatomical structure, comprising:

a handpiece;

an energy delivery device coupled to a distal portion of the handpiece including a tissue piercing distal end;

a safety stop positioned at an exterior of the energy delivery device; and

a cable coupled to the energy delivery device.

42. The apparatus of claim 41, wherein the safety stop defines a depth of penetration of the energy delivery device in the anatomical structure.

43. The apparatus of claim 41, wherein the safety stop defines an area of an energy delivery surface of the energy delivery device.

44. The apparatus of claim 41, wherein the safety stop includes a tissue interface surface.

45. The apparatus of claim 41, wherein the safety stop has a an exterior geometry section selected from a planar surface, a curved surface, a concave surface, a convex surface and combinations thereof.

46. The apparatus of claim 29, wherein the tissue interface surface applies a force to an energy delivery device insertion site of the anatomical structure.

47. The apparatus of claim 46, wherein the force immobilizes the tissue at the energy delivery device insertion site to facilitate a penetration of the energy delivery device into the anatomical structure.

48. The apparatus of claim 42, wherein the force creates a compression of the energy delivery device insertion site to facilitate a penetration of the energy delivery device into the anatomical structure.

49. The apparatus of claim 44, wherein an area of the tissue interface surface is in the range of 0.005 to 0.25 in^2.

50. The apparatus of claim 41, wherein the safety stop is adjustably mounted on an exterior of the energy delivery device.

51. The apparatus of claim 41, wherein the safety stop is configured to allow the advancement and retraction of the energy delivery device.

52. The apparatus of claim 51, wherein the safety stop includes an aperture for the advancement and retraction of the energy delivery device through the safety stop.

53. The apparatus of claim 41, wherein the anatomical structure is selected from a tongue, a turbinate, an uvula, a soft palate, and a tonsil.

54. The apparatus of claim 41, wherein the safety stop defines an energy delivery device energy delivery surface length.

55. An apparatus to treat a selected site in an interior of an anatomical structure, comprising:

an introducer;

an energy delivery device at least partially positionable in the interior of the introducer;

a pressure plate positioned at an exterior of the introducer; and

a cable coupled to the energy delivery device.

56. The apparatus of claim 55, wherein the pressure plate is positioned at a distal portion of the introducer.

57. The apparatus of claim 55, wherein the pressure plate is positioned at a distal end of the introducer.

58. The apparatus of claim 55, further comprising:

an advancement member coupled to the energy delivery device.

59. The apparatus of claim 55, wherein the apparatus reduces a volume of the selected site of the anatomical structure.

60. The apparatus of claim 55, wherein the apparatus alters a shape of the anatomical structure.

61. The apparatus of claim 55, wherein the energy delivery device is an RF electrode.

62. The apparatus of claim 61, further comprising:
an RF energy source coupled to the RF electrode.

63. The apparatus of claim 55, wherein the energy delivery device is a microwave antenna.

64. The apparatus of claim 63, further comprising:
a microwave energy source coupled to the microwave antenna.

65. The apparatus of claim 55, wherein the energy delivery device is a waveguide.

66. The apparatus of claim 65, further comprising:
a light source coupled to the waveguide.

67. The apparatus of claim 66, wherein the light source is a laser.

68. The apparatus of claim 55, wherein the energy delivery device is an acoustical transducer.

69. The apparatus of claim 68, further comprising:
an acoustical energy source coupled to the acoustical transducer.

70. The apparatus of claim 55, wherein the energy delivery device is a resistive heating device.

71. The apparatus of claim 70, further comprising:
an electrical current source coupled to the resistive heating device.

72. The apparatus of claim 55, further comprising:

a second energy delivery device coupled to a second introducer coupled to the handpiece.

73. The apparatus of claim 72, further comprising:

a second pressure plate positioned at an exterior of the second introducer.

74. The apparatus of claim 55, wherein the energy delivery device includes an infusion lumen.

75. The apparatus of claim 74, wherein the infusion lumen is coupled to a medication source.

76. The apparatus of claim 74, wherein the infusion lumen is coupled to a contrast medium source.

77. The apparatus of claim 74, wherein the infusion lumen is coupled to a electrolytic solution source.

78. The apparatus of claim 74, wherein the infusion lumen is coupled to a disinfectant source.

79. The apparatus of claim 55, further comprising:

a cooling device coupled to the energy delivery device.

80. The apparatus of claim 55, further comprising:

an insulator positioned at an exterior of the energy delivery device.

81. The apparatus of claim 55, further comprising:

a sensor coupled to the energy delivery device.

82. The apparatus of claim 81, wherein the sensor is positioned at a distal portion of the energy delivery device.

83. The apparatus of claim 55, further comprising:

a feedback control device coupled to the energy delivery device, a sensor and an energy source.

84. The apparatus of claim 55, wherein the pressure plate defines a depth of penetration of the energy delivery device in the anatomical structure.

85. The apparatus of claim 55, wherein the pressure plate defines an area of an energy delivery surface of the energy delivery device.

86. The apparatus of claim 55, wherein the pressure plate includes a tissue interface surface.

87. The apparatus of claim 55, wherein the pressure plate has an exterior geometry section selected from a planar surface, a curved surface, a concave surface, a convex surface and combinations thereof.

88. The apparatus of claim 86, wherein the tissue interface surface applies a force to an energy delivery device insertion site of the anatomical structure.

89. The apparatus of claim 88, wherein the force immobilizes the tissue at the energy delivery device insertion site to facilitate a penetration of the energy delivery device into the anatomical structure.

90. The apparatus of claim 88, wherein the force creates a compression of the energy delivery device insertion site to facilitate a penetration of the energy delivery device into the anatomical structure.

91. The apparatus of claim 86, wherein an area of the tissue interface surface is in the range of 0.005 to 0.25 in^2.

92. The apparatus of claim 55, wherein the pressure plate is adjustably mounted on an exterior of the introducer.

93. The apparatus of claim 55, wherein the pressure plate is configured to allow the advancement and retraction of the energy delivery device.

94. The apparatus of claim 93, wherein the pressure plate includes an aperture for the advancement and retraction of the energy delivery device through the pressure plate.

95. The apparatus of claim 55, wherein the anatomical structure is selected from a tongue, a turbinate, a uvula, a soft palate, and a tonsil.

96. The apparatus of claim 55, wherein the energy delivery device is sufficiently sharp to pierce an exterior surface of the anatomical member without a support device.

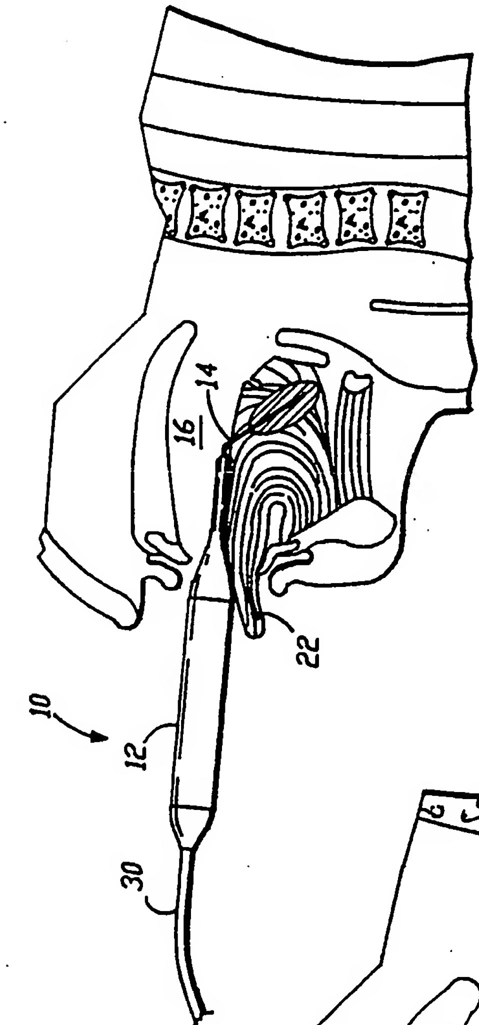
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FIG. — 1A

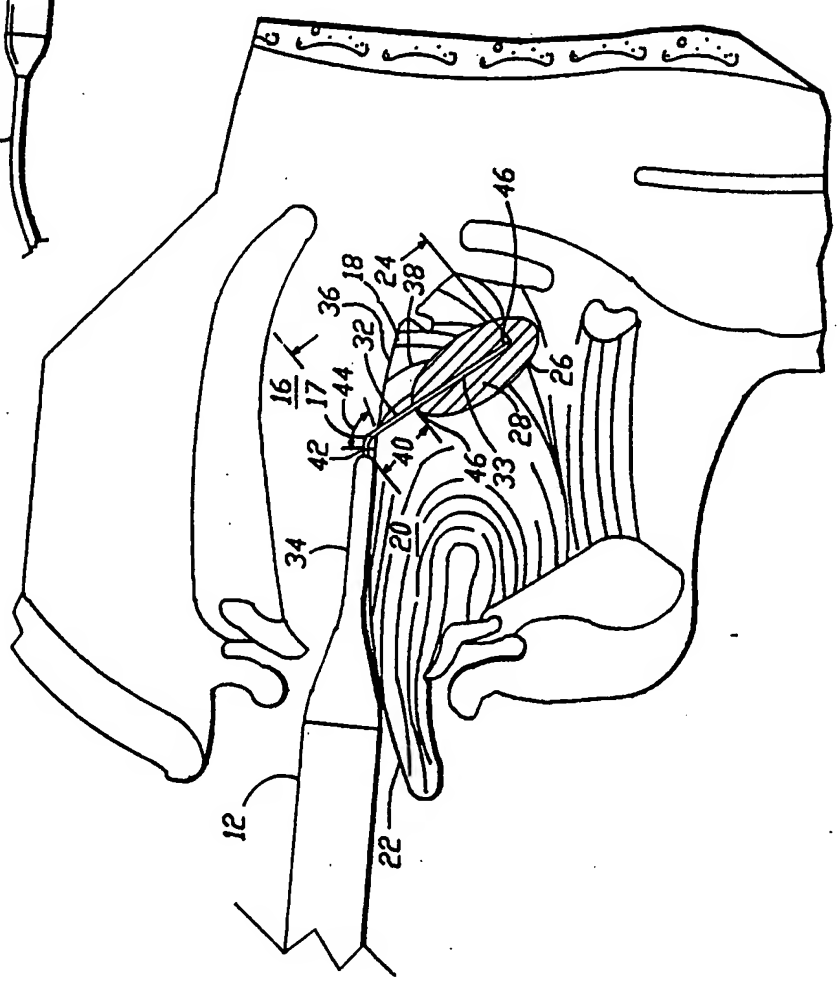
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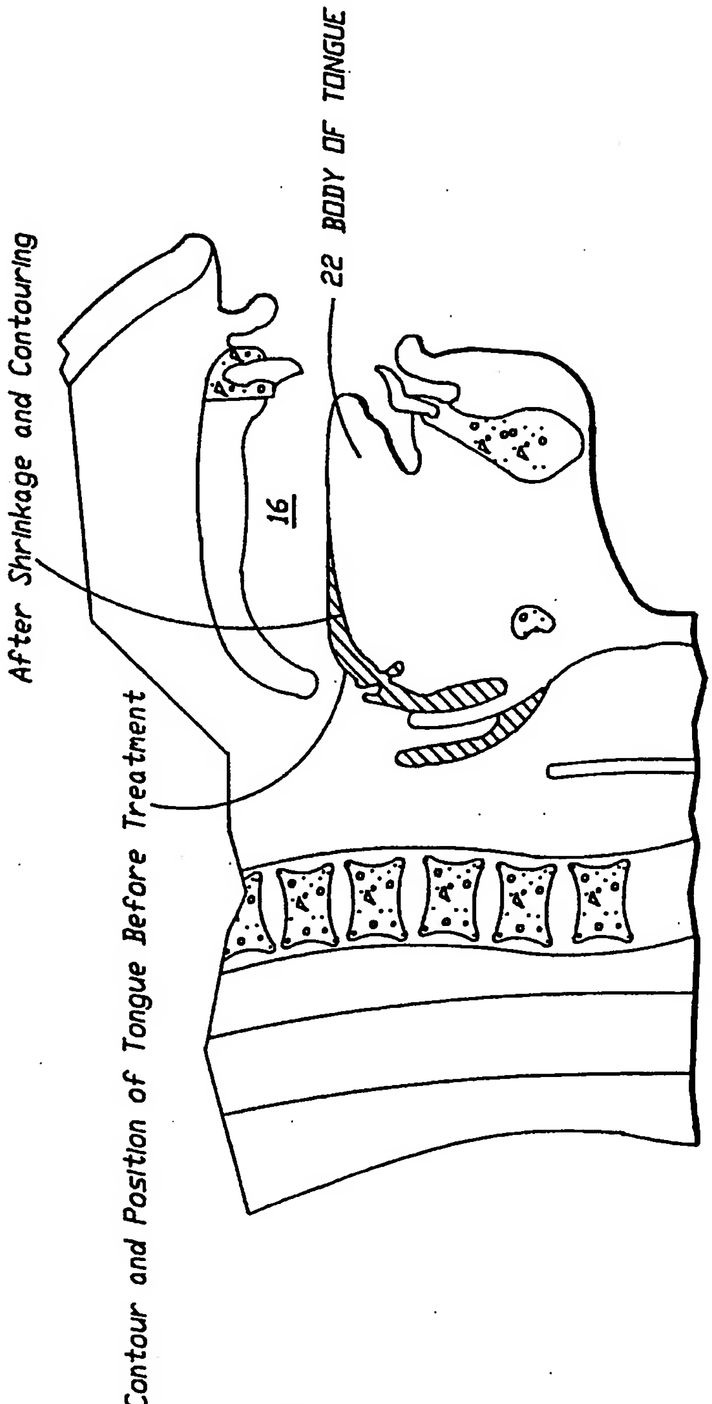
FIG. — 1B



LATERAL VIEW OF NASAL CAVITY, MOUTH, SPINE

FIG. —1C

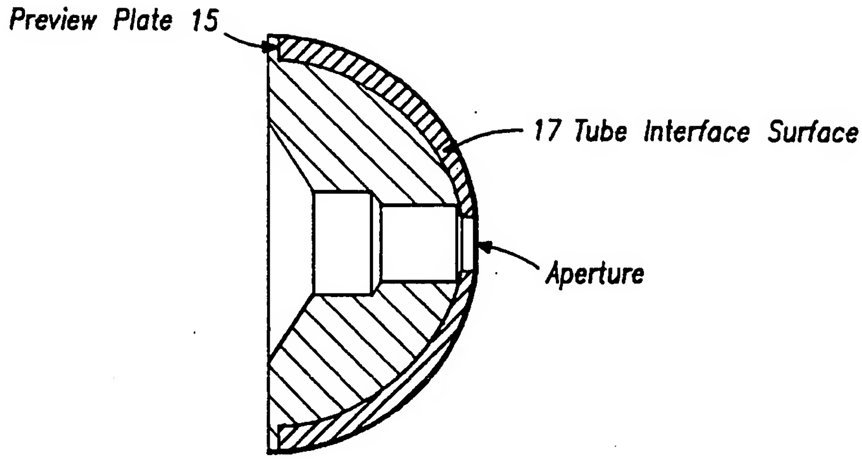

Preview Plate 15
17 Tube Interface Surface
Aperture

FIG. –2A

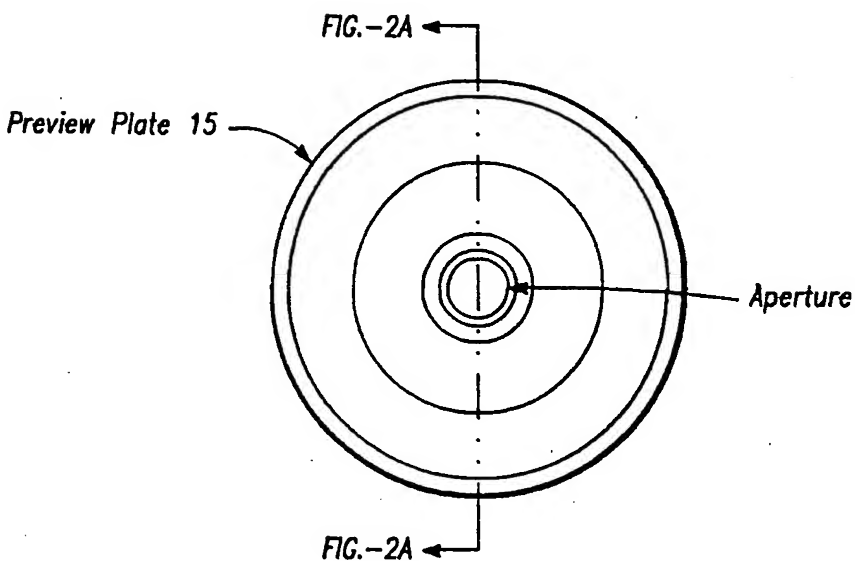


FIG.–2A
Preview Plate 15
Aperture
FIG.–2A

FIG. –2B

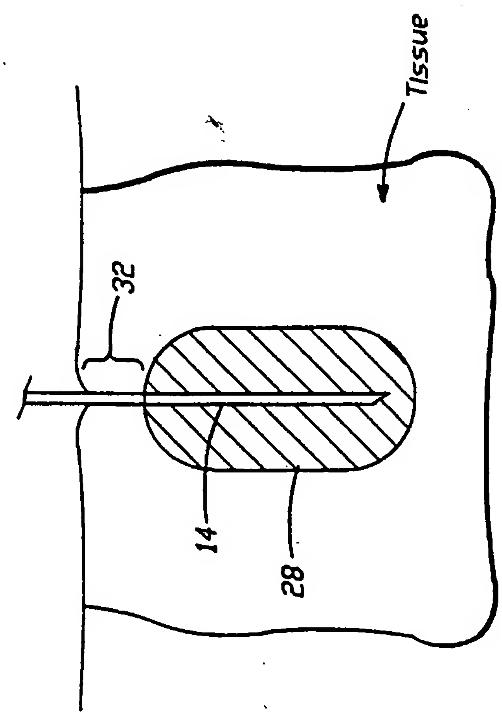


FIG. —3A

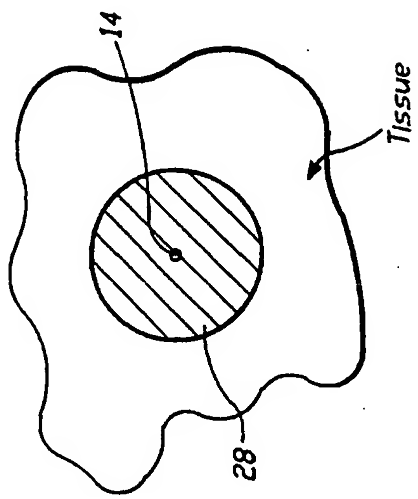


FIG. —3B

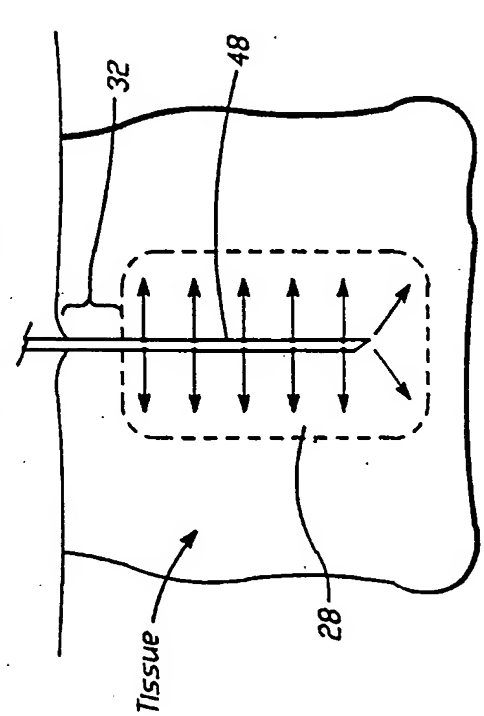


FIG. —4

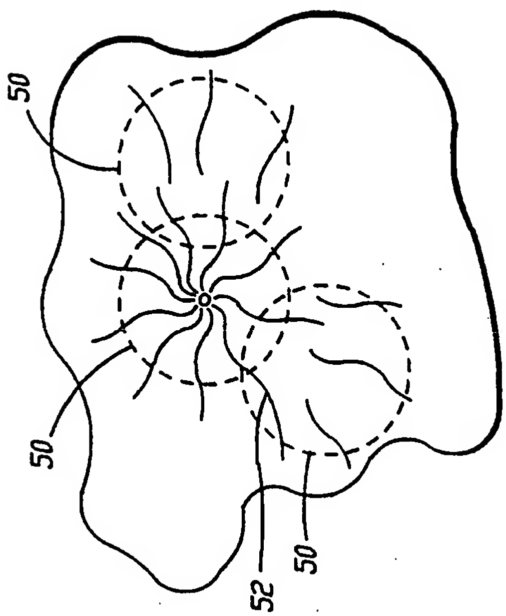


FIG. —5

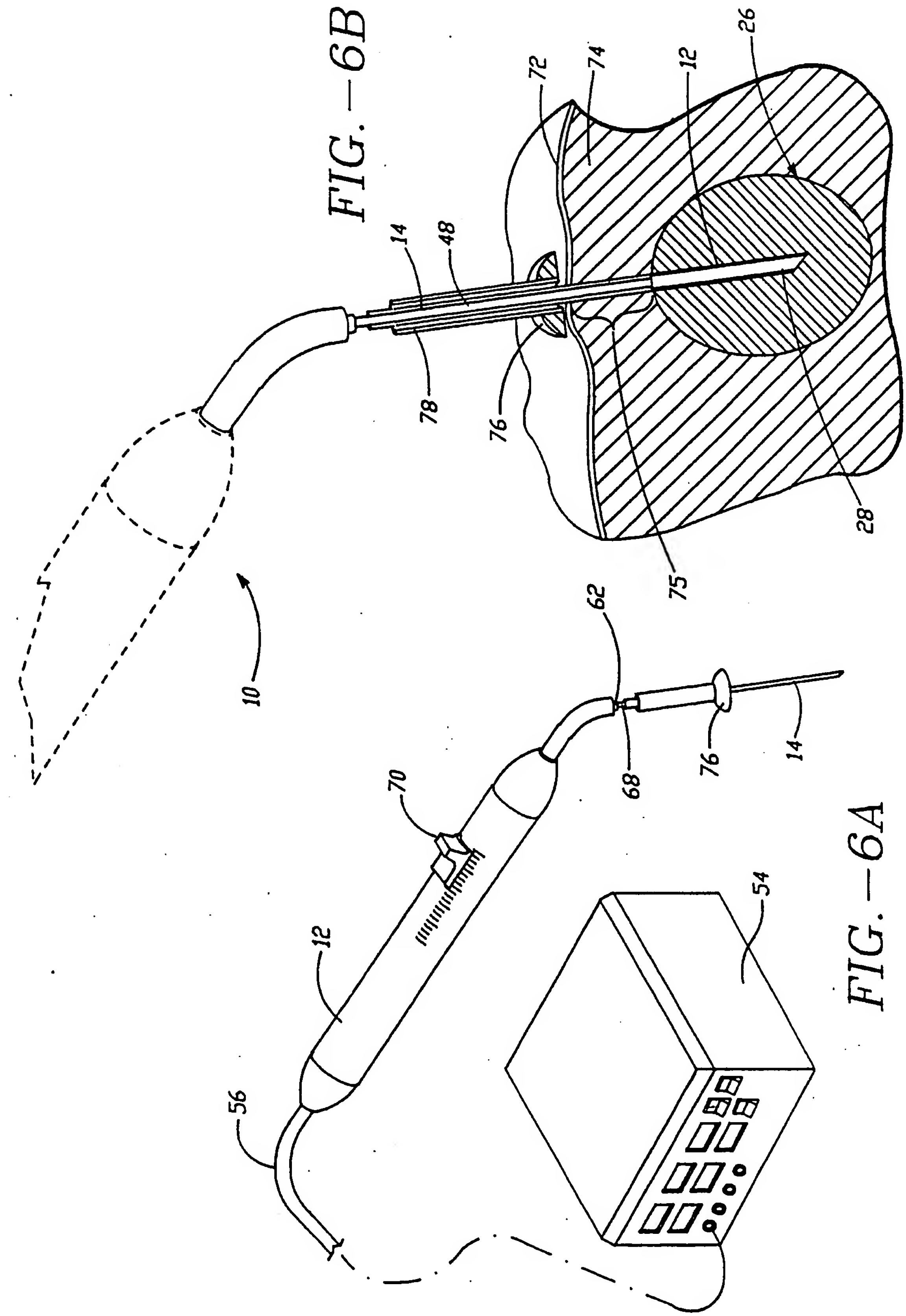


FIG. —6B

FIG. —6A

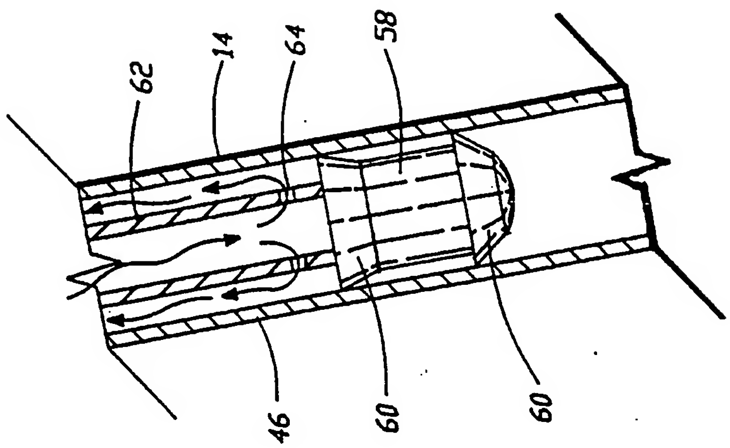


FIG. —8

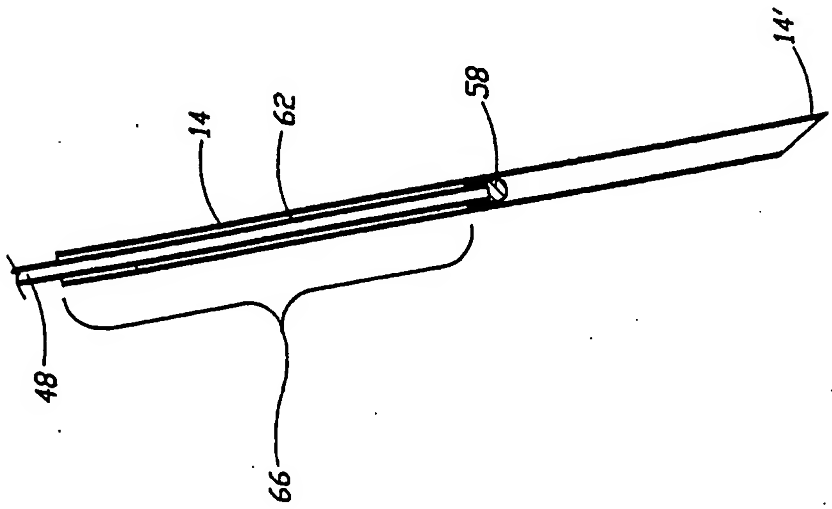


FIG. —7

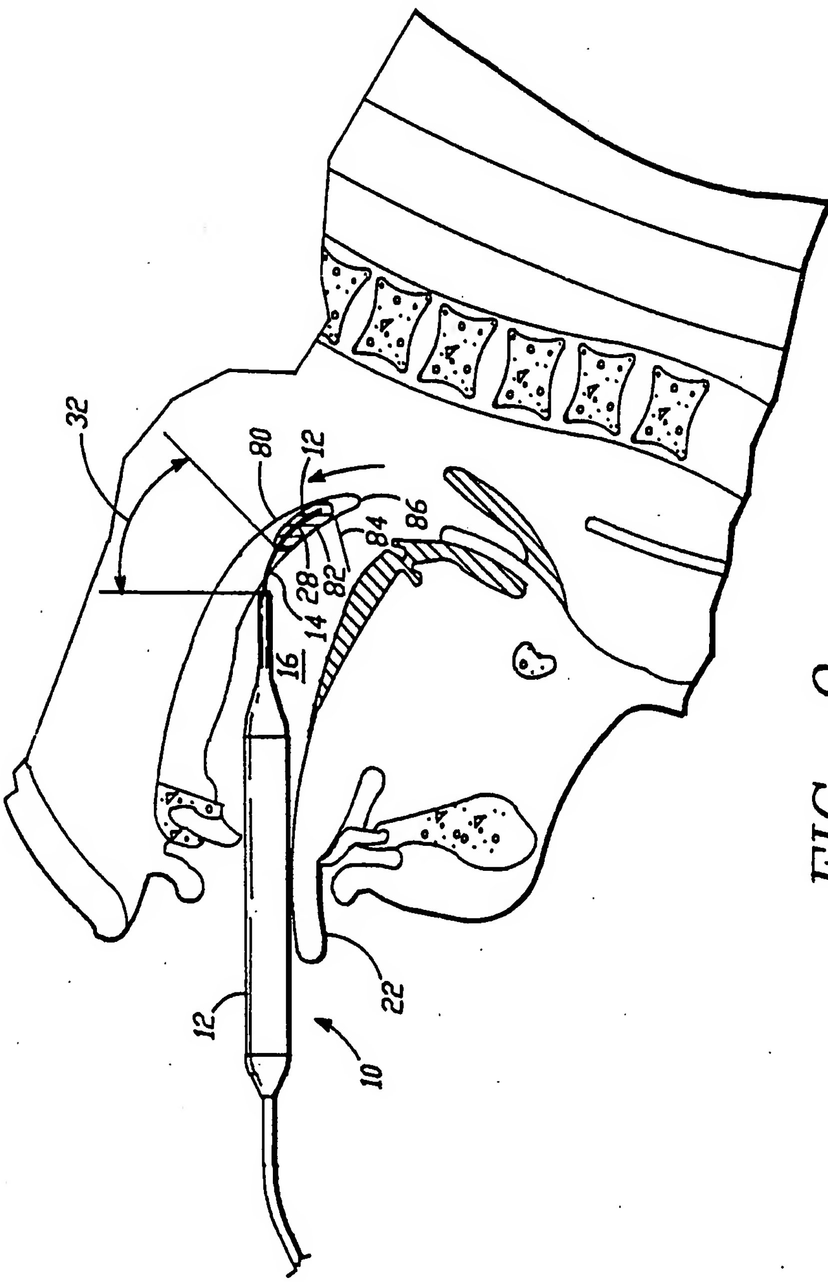


FIG. — 9

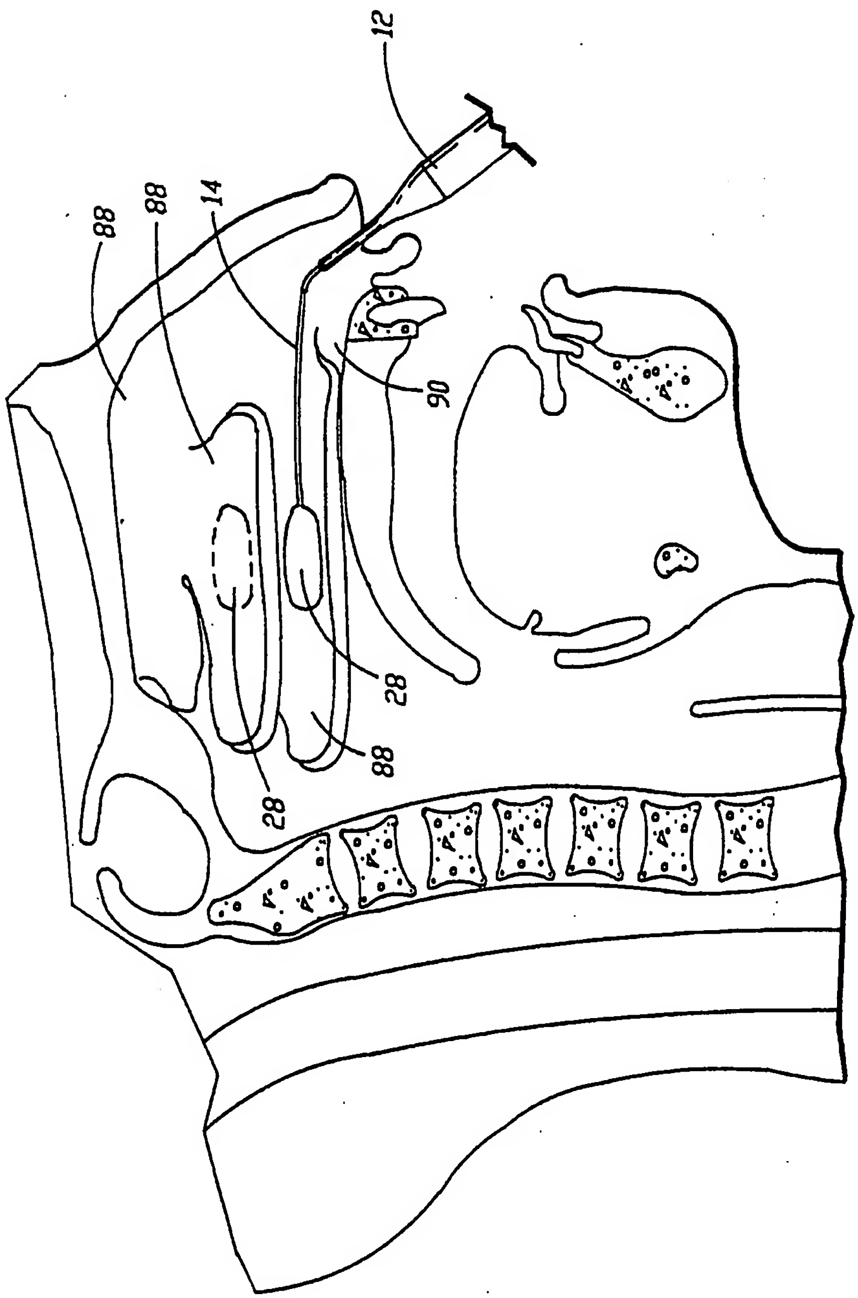


FIG. — 10

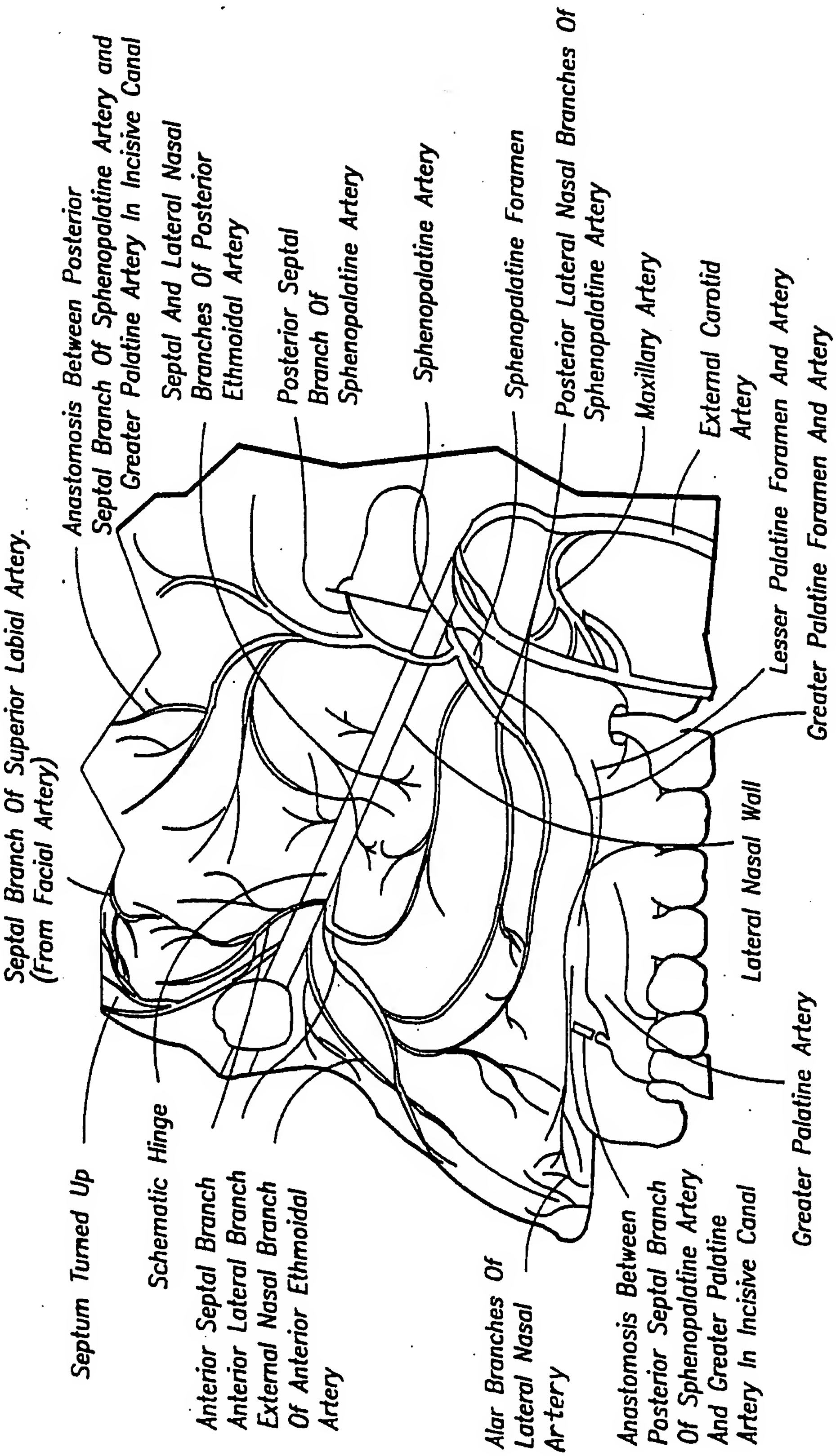

Septal Branch Of Superior Labial Artery. (From Facial Artery)
Anastomosis Between Posterior Septal Branch Of Sphenopalatine Artery and Greater Palatine Artery In Incisive Canal
Septal And Lateral Nasal Branches Of Posterior Ethmoidal Artery
Posterior Septal Branch Of Sphenopalatine Artery
Sphenopalatine Artery
Sphenopalatine Foramen
Posterior Lateral Nasal Branches Of Sphenopalatine Artery
Maxillary Artery
External Carotid Artery
Lesser Palatine Foramen And Artery
Greater Palatine Foramen And Artery
Lateral Nasal Wall
Greater Palatine Artery
Septum Turned Up
Schematic Hinge
Anterior Septal Branch Anterior Lateral Branch External Nasal Branch Of Anterior Ethmoidal Artery
Alar Branches Of Lateral Nasal Artery
Anastomosis Between Posterior Septal Branch Of Sphenopalatine Artery And Greater Palatine Artery In Incisive Canal

FIG. – 11

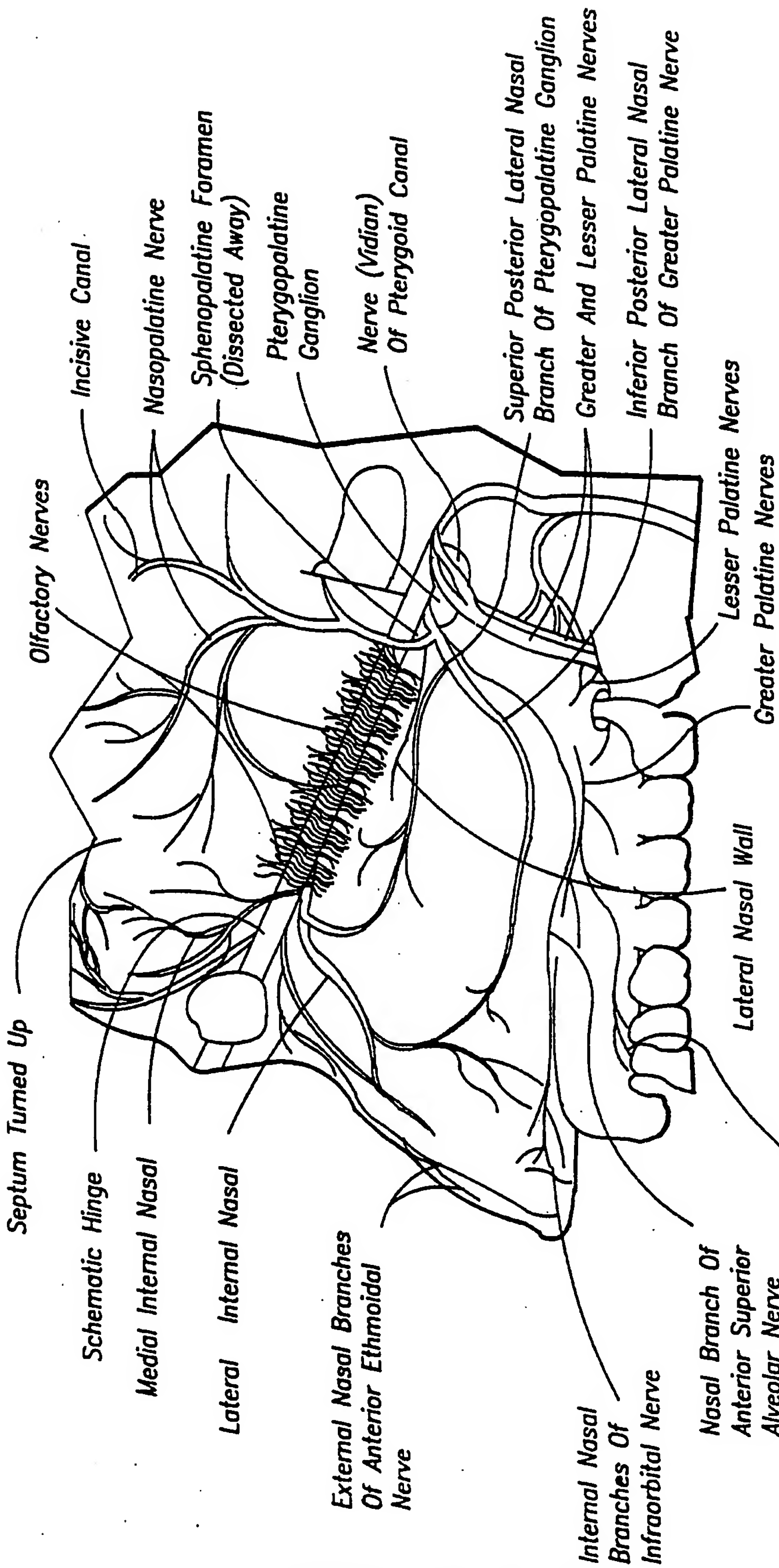

Incisive Canal
Nasopalatine Nerve
Sphenopalatine Foramen (Dissected Away)
Pterygopalatine Ganglion
Nerve (Vidian) Of Pterygoid Canal
Superior Posterior Lateral Nasal Branch Of Pterygopalatine Ganglion
Greater And Lesser Palatine Nerves
Inferior Posterior Lateral Nasal Branch Of Greater Palatine Nerve
Lesser Palatine Nerves
Greater Palatine Nerves
Olfactory Nerves
Lateral Nasal Wall
Septum Turned Up
Schematic Hinge
Medial Internal Nasal
Lateral Internal Nasal
External Nasal Branches Of Anterior Ethmoidal Nerve
Internal Nasal Branches Of Infraorbital Nerve
Nasal Branch Of Anterior Superior Alveolar Nerve
Communication Between Greater Palatine And Nasopalatine Nerves At Incisive Canal

FIG. — 12

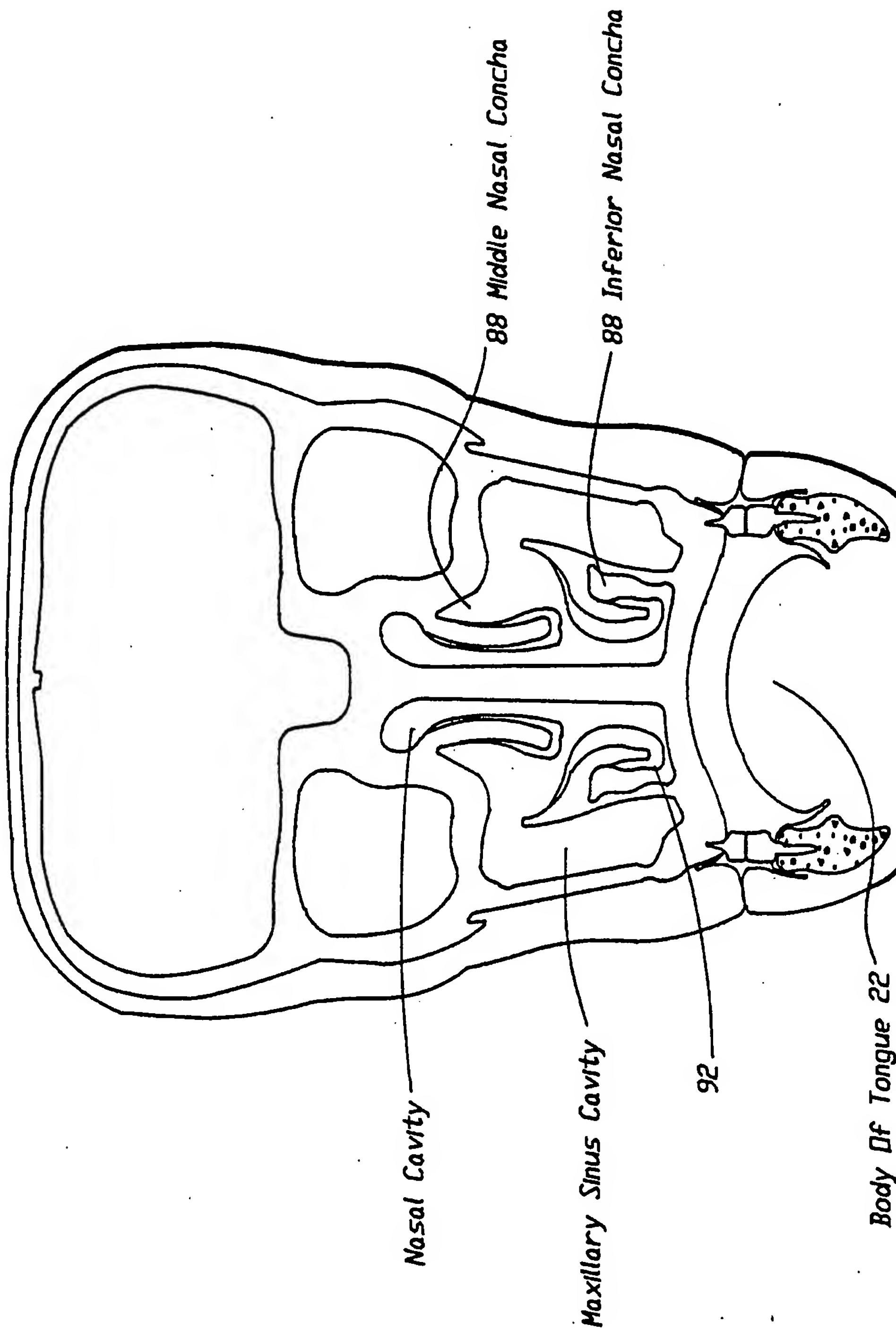

88 Middle Nasal Concha
88 Inferior Nasal Concha
Nasal Cavity
Maxillary Sinus Cavity
92
Body Of Tongue 22

FIG. — 13

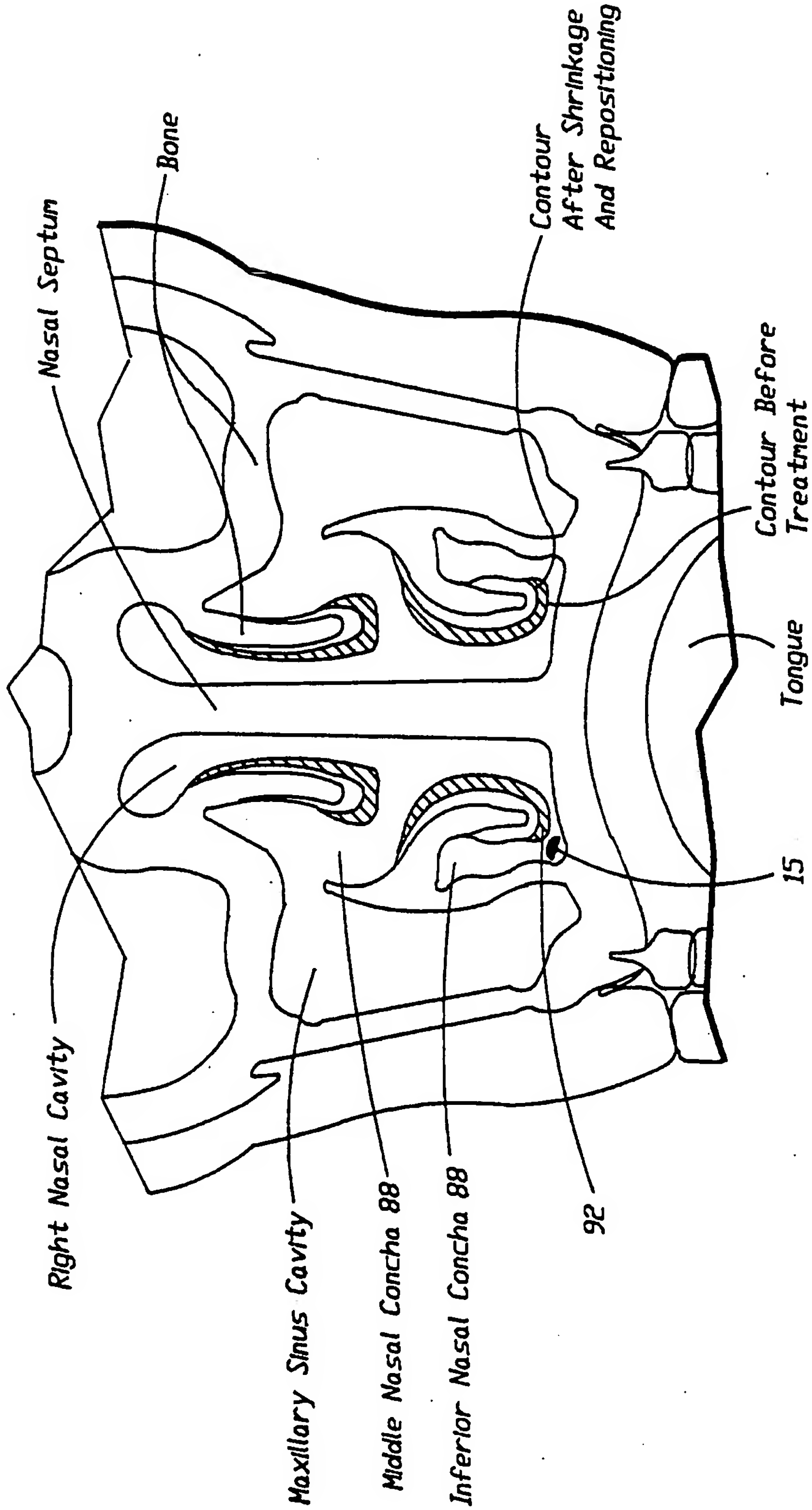

Nasal Septum
Bone
Contour
After Shrinkage
And Repositioning
Contour Before
Treatment
Tongue
15
92
Inferior Nasal Concha 88
Middle Nasal Concha 88
Maxillary Sinus Cavity
Right Nasal Cavity

FIG. — 14

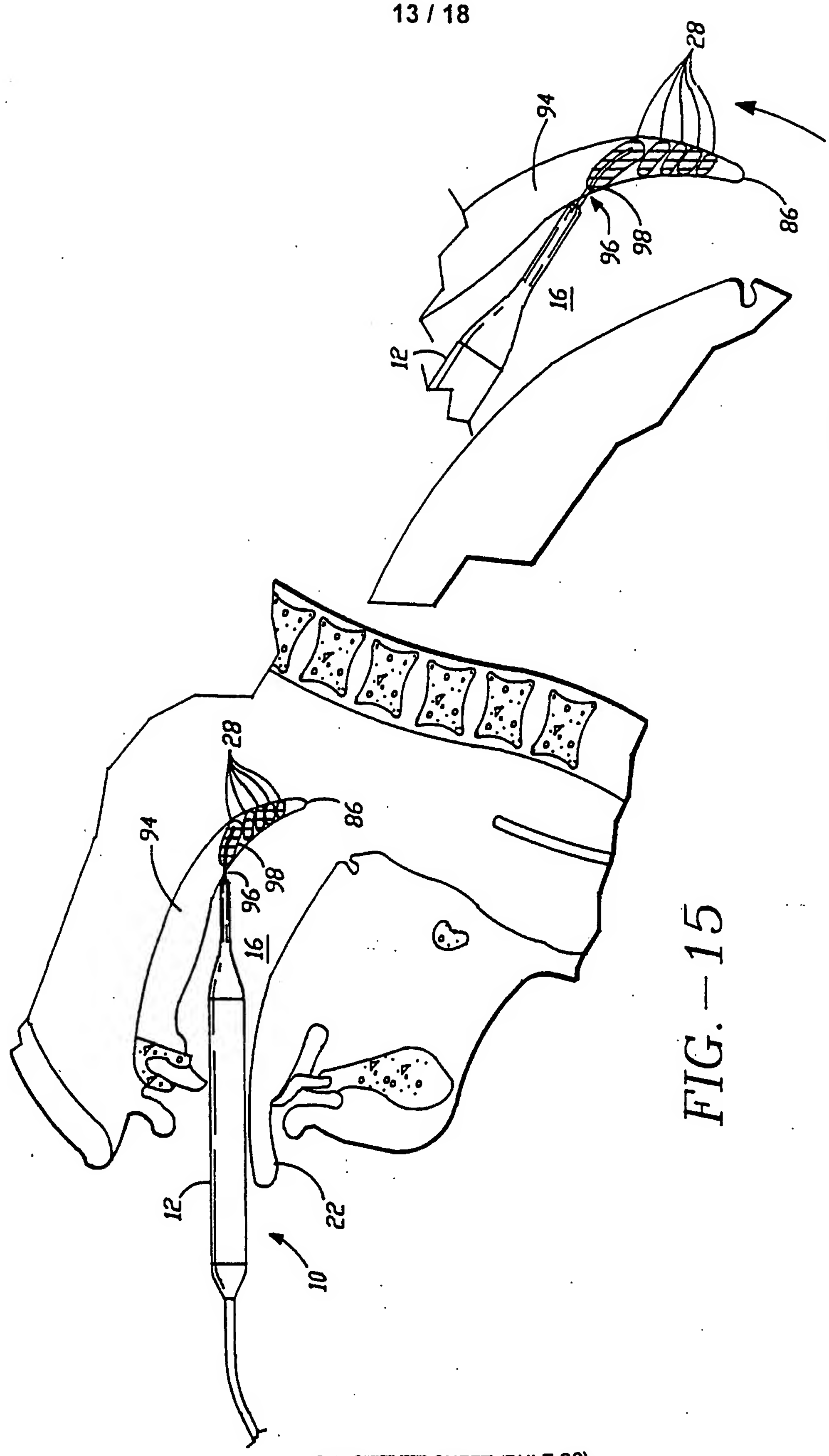


FIG. — 16

FIG. — 15

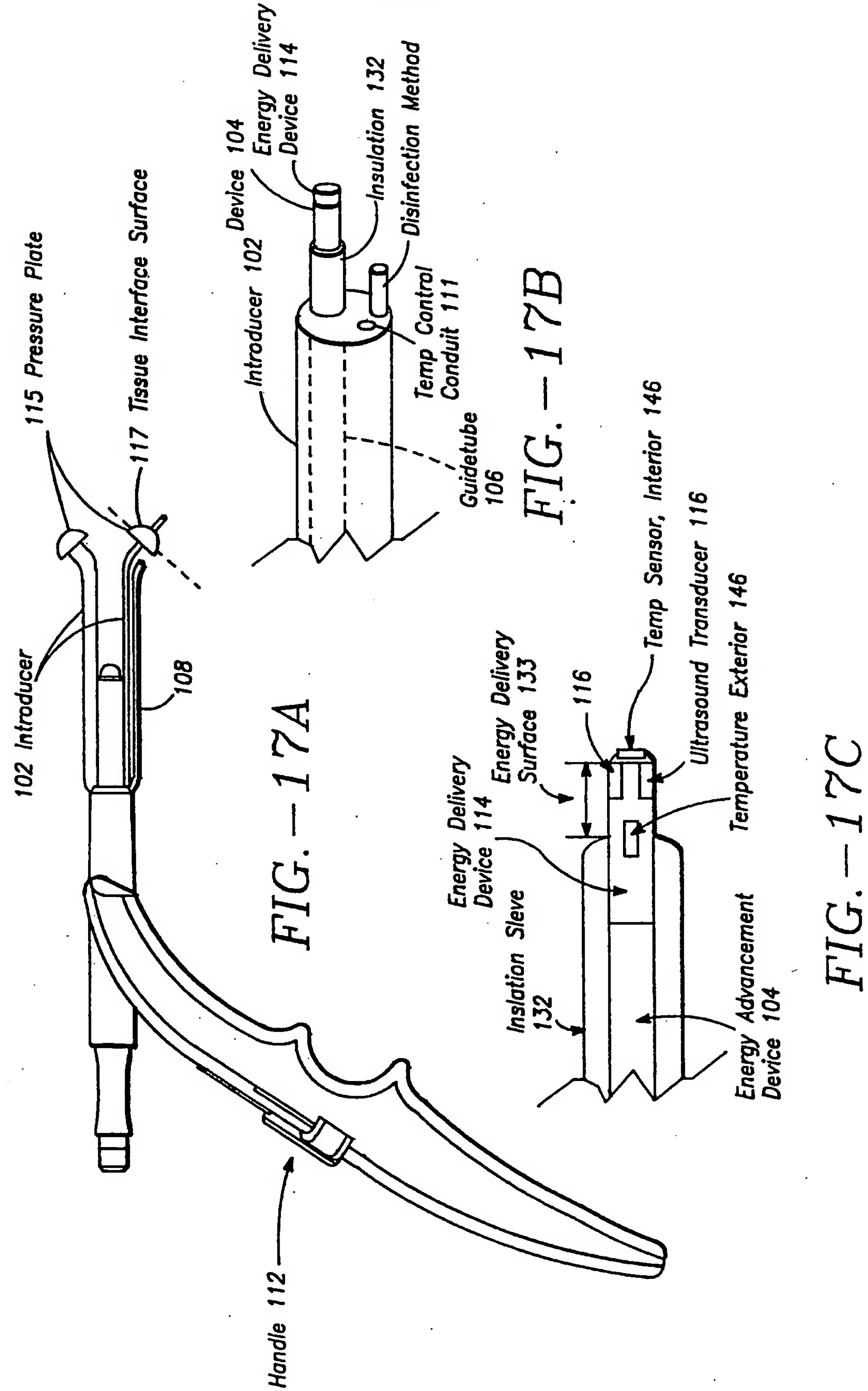


FIG. — 17A

FIG. — 17B

FIG. — 17C

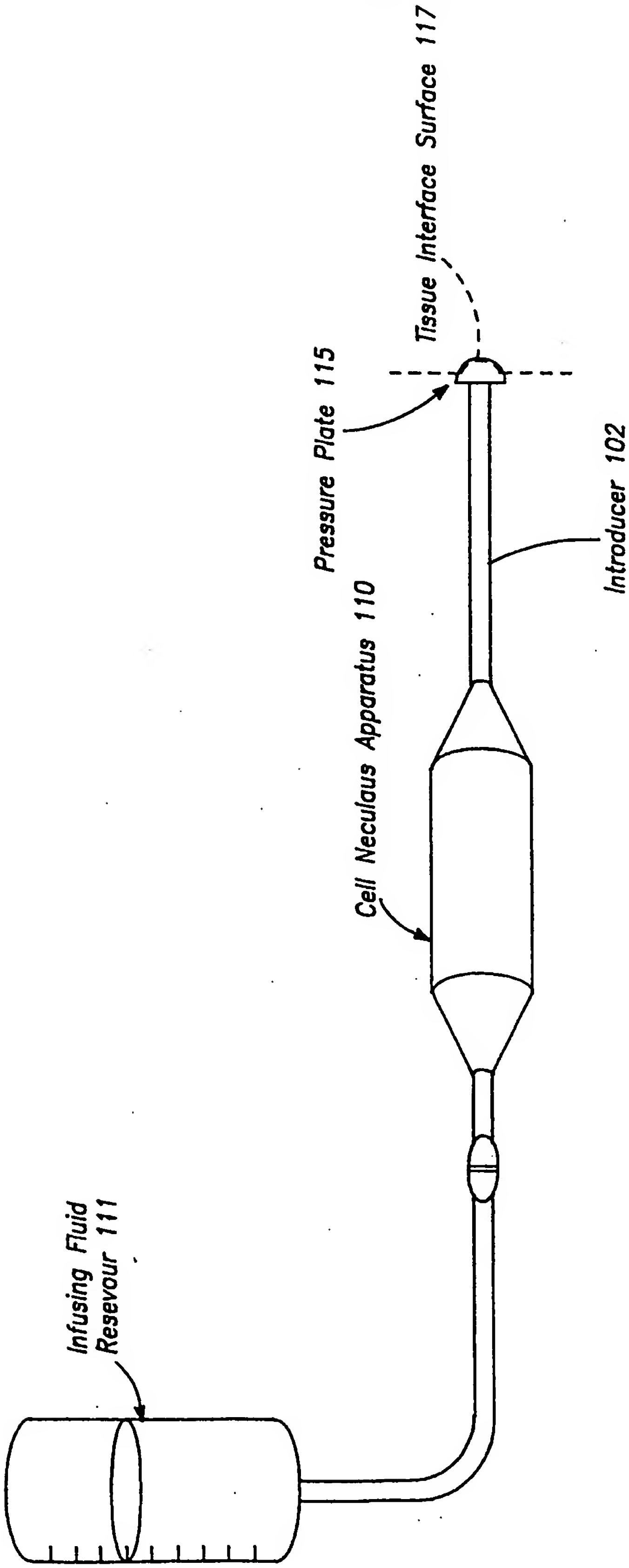

Tissue Interface Surface 117
Pressure Plate 115
Introducer 102
Cell Neculaus Apparatus 110
Infusing Fluid
Resevour 111

FIG. – 17D

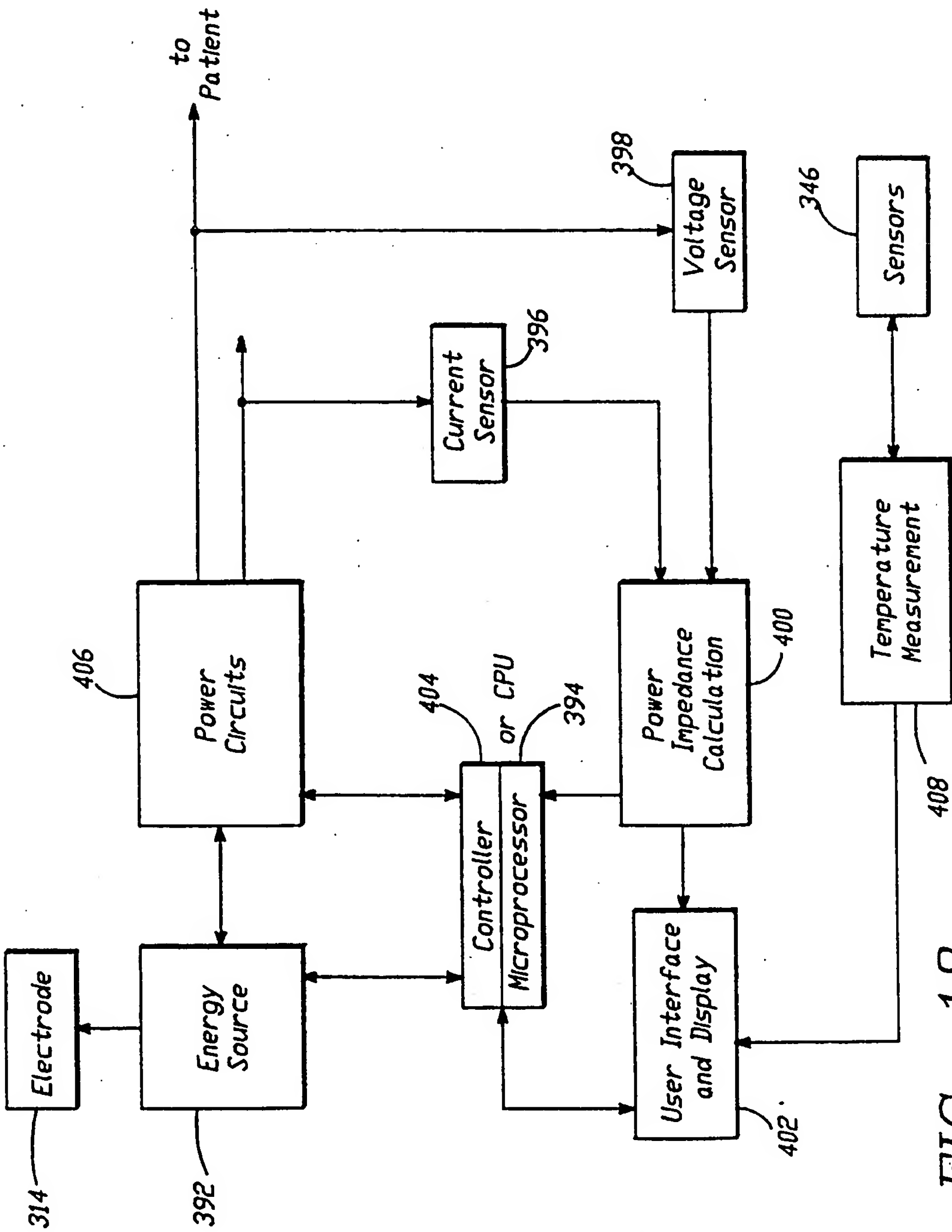
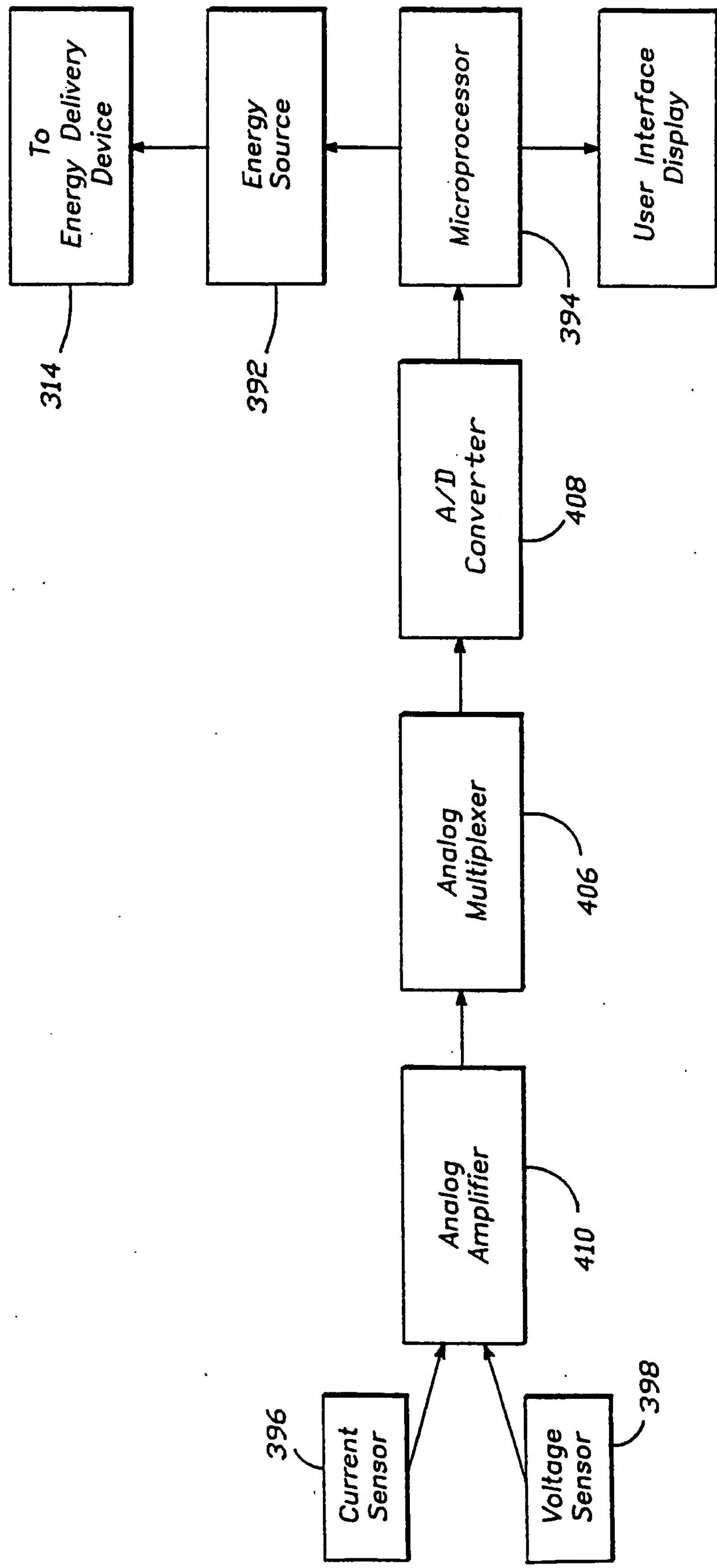

to Patient
398
Voltage Sensor
346
Sensors
396
Current Sensor
406
Power Circuits
404
Controller
or CPU
Microprocessor
394
Power Impedance Calculation
400
Temperature Measurement
408
Electrode
Energy Source
User Interface and Display
314
392
402

FIG. — 18



To Energy Delivery Device
Energy Source
Microprocessor
User Interface Display
A/D Converter
Analog Multiplexer
Analog Amplifier
Current Sensor
Voltage Sensor
314
392
394
402
408
406
410
396
398

FIG. — 19

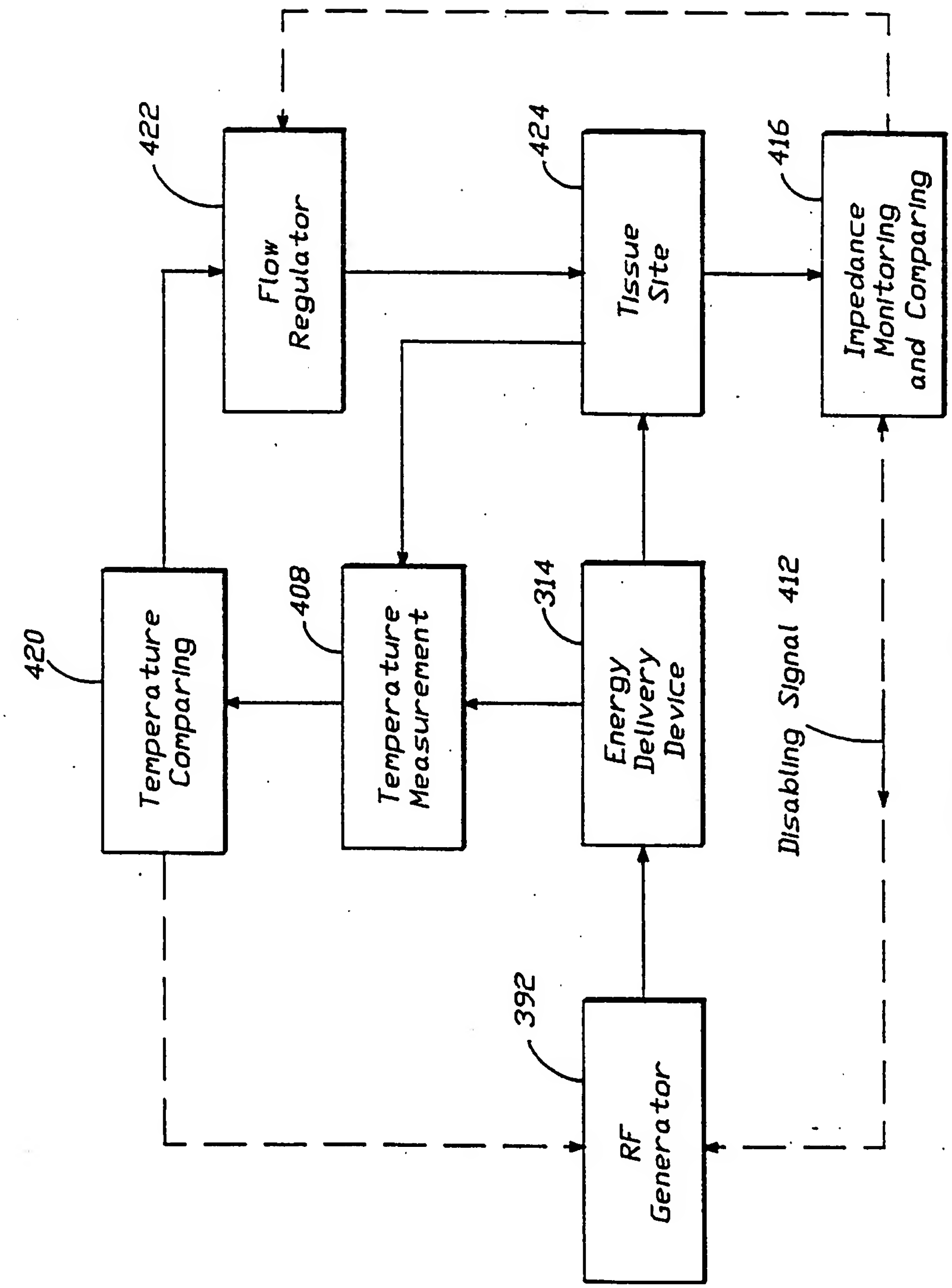

Flow Regulator
422
Tissue Site
424
Impedance Monitoring and Comparing
416
Temperature Comparing
420
Temperature Measurement
408
Energy Delivery Device
314
Disabling Signal 412
RF Generator
392

FIG. —20

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/26144

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y A	WO 97 43973 A (SOMNUS) 27 November 1997 see the whole document ---	1,41,55 1-96
Y	US 5 147 308 A (SINGER ANDREW) 15 September 1992 see the whole document ---	1,41,55
A,P	US 5 743 904 A (EDWARDS STUART D) 28 April 1998 ref sign 130 ---	1,41,55
A,P	US 5 800 379 A (EDWARDS) 1 September 1998 see the whole document ---	1-96
A	US 5 203 866 A (ISLAM ABUL B M A) 20 April 1993 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 April 1999	10/05/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Papone, F

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/26144

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			AU	3119597	A	26-11-1997
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			AU	3145597	A	09-12-1997
			AU	6850696	A	09-12-1997
			CA	2253847	A	27-11-1997
			EP	0901398	A	17-03-1999
			WO	9743969	A	27-11-1997
			WO	9730646	A	28-08-1997
			WO	9741789	A	13-11-1997
			WO	9744092	A	27-11-1997
			WO	9743972	A	27-11-1997
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			US	5800379	A	01-09-1998
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			WO	9730646	A	28-08-1997
			WO	9744092	A	27-11-1997
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			AU	2070897	A	26-11-1997
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 98/26144

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